ERIK J. STEMMY



- NIH PRINCIPLE INVESTIGATOR
- VIRAL ARI) RESPIRATORY DISEASES BRANCH DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES, NIAID/NIH

An official website of the United States government Here's how you know

2023 Award Winner

Erik Stemmy

STEMMY

2023 Awards Summary

1

Group Award Won

NIAID (National Institute of Allergy and Infectious Diseases)

Scientific/Medical - Research

Group Awards

SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program Group

In recognition of significant contributions to the real-time assessment of emerging SARS-CoV-2 mutations that could impact transmissibility, virulence, and susceptibility to infection or vaccine-induced immunity.

HTTPS://DIRECTORSAWARDS.HR.NIH.GOV/AWARDS/2023/WINNERS/S/SAFF04EFEF52FE037DC4438A43E0D567F/

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Year	Occupation	Paygrade	Base Salary	Bonus	Location
2022	General Health Science	GS-14	$155,687	$0	Rockville, Maryland
2021	General Health Science	GS-14	$151,118	$0	Rockville, Maryland
2020	General Health Science	GS-14	$145,578	$0	Rockville, Maryland
2019	General Health Science	GS-14	$136,725	$0	Rockville, Maryland
2018	General Health Science	GS-14	$129,869	$0	Rockville, Maryland
2017	General Health Science	GS-14	$126,958	$0	Rockville, Maryland
2016	General Health Science	GS-14	$116,146	$0	Rockville, Maryland
2015	General Health Science	GS-14	$110,902	$0	Rockville, Maryland
2014	General Health Science	GS-13	$89,924	$0	Bethesda, Maryland

In 2022, Erik J. Stemmy was a General Health Scientist at the National Institutes of Health in Rockville, Maryland. Stemmy began working at the National Institutes of Health in 2011 with a starting salary of $62,467. Since then, Stemmy's salary has increased to $155,687 in 2022.

Erik J. Stemmy is a GS-14 under the general schedule payscale.

Erik J. Stemmy's 2022 pay is

↑ 36%

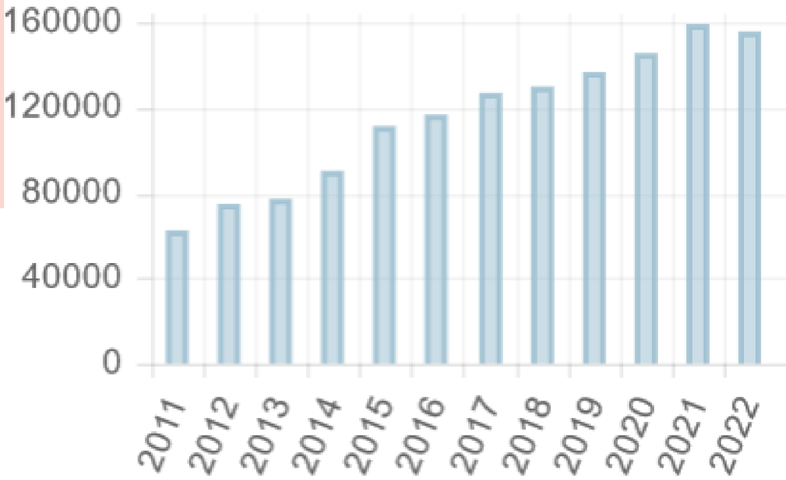
higher than the average General Health Scientist across all agencies.

Erik J. Stemmy's 2022 pay is

↑ 118%

higher than the average pay of a GS employee at the National Institutes of Health.

Erik J. Stemmy's pay trend during his or her government career in the National Institutes of Health:



STEMMY

https://www.federalpay.org/employees/national-institutes-of-health/stemmy-erik-j

STEMMY

The George Washington University
Ph.D., Immunology
2006 - 2011

Activities and societies: Institute for Biomedical Sciences

Dissertation topic: Characterizing the role of extracellular cyclophilins in chronic allergic asthma.

Georgetown University
M.S., Microbiology and Science Policy
2003 - 2005

Licenses & certifications

Certification for Contracting Officer's Representatives Level III (FAC-COR)
United States Federal Government
Issued Aug 2018

Experience

STEMMY

National Institute of Allergy and Infectious Diseases (NIAID)
Full-time · 13 yrs 2 mos

Team Lead
Sep 2022 - Present · 1 yr 8 mos
Hybrid

Team Lead managing NIAID's Centers of Excellence for Influenza Research and Response (CEIRR) Network, a global multi-disciplinary network focused on understanding influenza natura ...see more

Immunology, Research and +3 skills

CEIRR Network
NIAID-funded Centers of Excellence for Influenza Research and Response Network

Program Officer
Mar 2011 - Feb 2023 · 12 yrs

Program Officer in the Viral Respiratory Diseases Section of the Respiratory Diseases Branch in NIAID's Division of Microbiology and Infectious Diseases. I manage a diverse grant and contract research portfolio covering Rhinoviruses and Human Coronaviruses, including basic research, therapeutic & vaccine development, and pre/clinical testing. I also manage the Data Processing and Coordination Center for NIAID's Centers of Excellence for Influenza Research and Surveillance, a global network of researchers investigating influenza pathogenesis, transmission, and evolution.

https://grantome.com/search?q=erik+stemmy

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69	2020
29	2021
29	2018
28	2019
25	2014
24	2015
22	2016
20	2017
18	2013
18	2012
8	2010

Grantome

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'Stemmy, Erik J'

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Funder

Year

69	2020
29	2021
29	2018
28	2019
25	2014
24	2015
22	2016
20	2017

Search

Show 10 entries

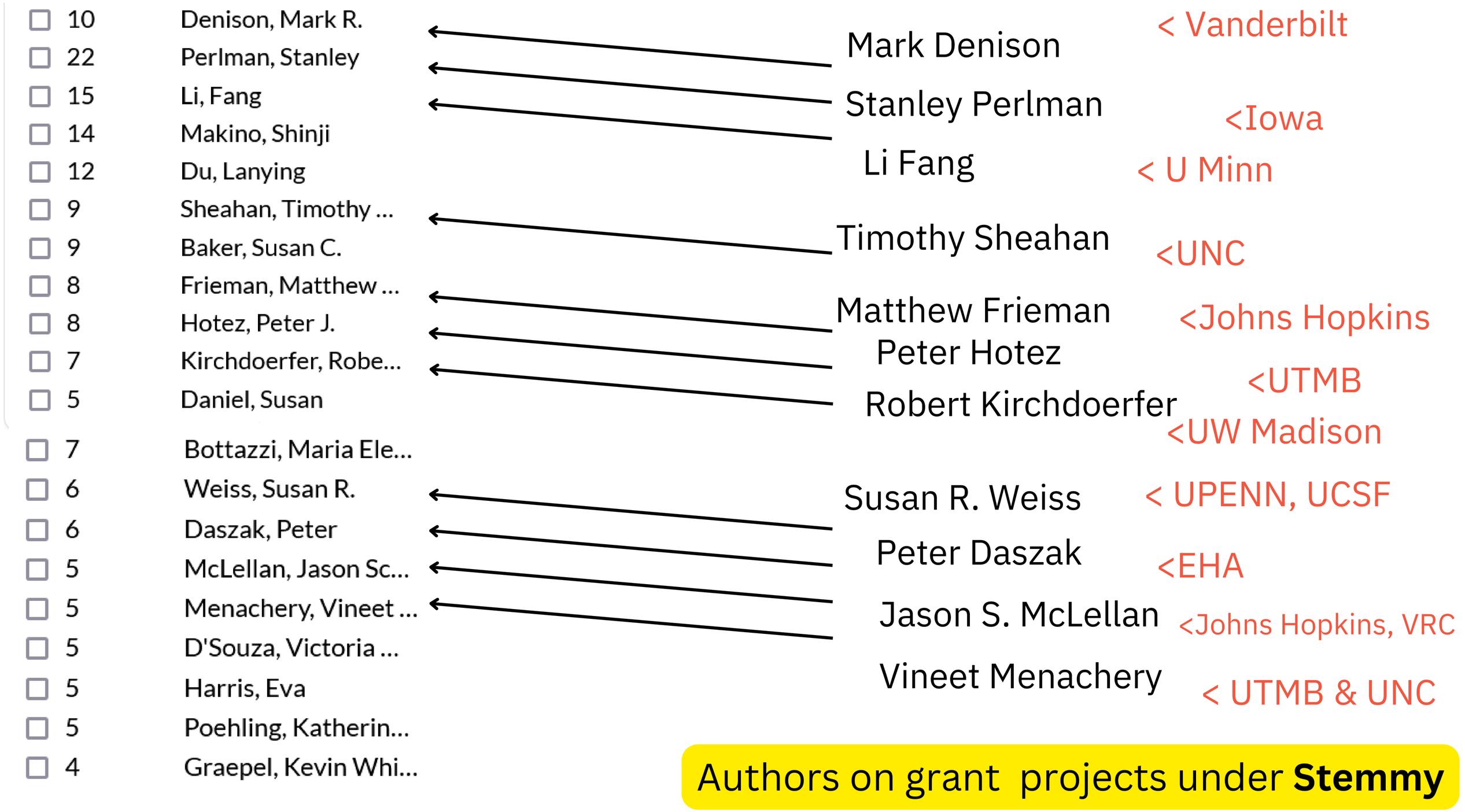
Previous | 1 | 2 | 3 | 4 | 5 | ... | Next

NIH 2021 R00 AI
Structural Studies of the Coronavirus Life Cycle
Kirchdoerfer, Robert Nicholas / University of Wisconsin Madison

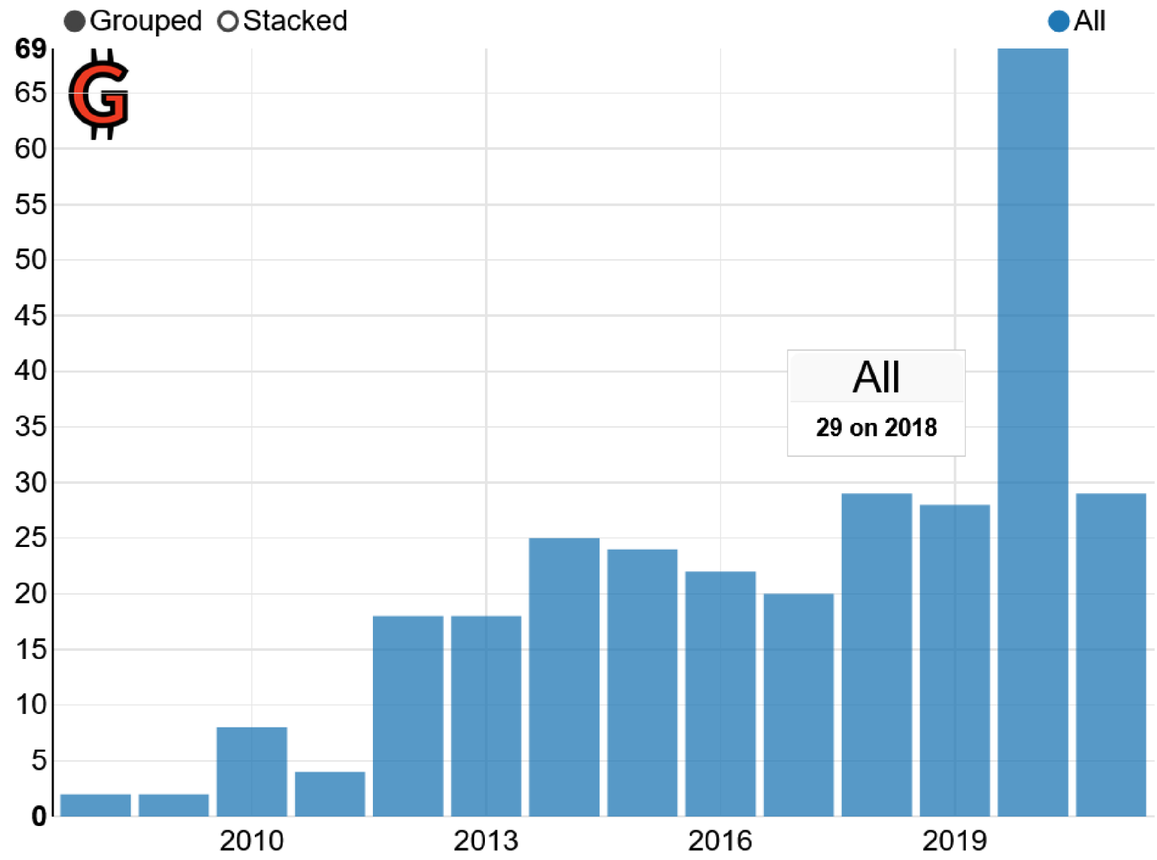
NIH 2021 R01 AI
Rational design and evaluation of novel mRNA vaccines against MERS-CoV
Du, Lanying / New York Blood Center

NIH 2021 R21 AI
Accelerating discovery of neutralizing paratopes with Functional Antibody Screening Technology
De Figueiredo, Paul; Han, Arum / Texas A&M University

NIH 2021 R21 AI
Rhinovirus C Infection in Normal and Asthmatic Human Airway Epithelium at Single Cell Resolution
Scull, Margaret Adele; Rosenberg, Brad / University of Maryland College Park


10 Denison, Mark R.
22 Perlman, Stanley
15 Li, Fang
14 Makino, Shinji
12 Du, Lanying
9 Sheahan, Timothy ...
9 Baker, Susan C.
8 Frieman, Matthew ...
8 Hotez, Peter J.
7 Kirchdoerfer, Robe...
5 Daniel, Susan
7 Bottazzi, Maria Ele...
6 Weiss, Susan R.
6 Daszak, Peter
5 McLellan, Jason Sc...
5 Menachery, Vineet ...
5 D'Souza, Victoria ...
5 Harris, Eva
5 Poehling, Katherin...
4 Graepel, Kevin Whi...
Mark Denison
< Vanderbilt
Stanley Perlman
<Iowa
Li Fang
< U Minn
Timothy Sheahan
<UNC
Matthew Frieman
<Johns Hopkins
Peter Hotez
<UTMB
Robert Kirchdoerfer
<UW Madison
Susan R. Weiss
< UPENN, UCSF
Peter Daszak
<EHA
Jason S. McLellan
<Johns Hopkins, VRC
Vineet Menachery
< UTMB & UNC
Authors on grant projects under **Stemmy**

☐	24	University of Nort…
☐	20	University of Iowa
☐	19	Vanderbilt Univers…
☐	13	University of Maryl…
☐	12	New York Blood C…
☐	11	University of Penn…
☐	11	University of Texas…
☐	9	Baylor College of …
☐	9	Loyola University …
☐	8	University of Wisc…
☐	8	University of Minn…
☐	8	Harvard University
☐	7	University of Texas…
☐	7	Cornell University
☐	6	Ecohealth Alliance,…
☐	5	University of Maryl…
☐	5	University of Califo…
☐	5	Wake Forest Unive…
☐	4	Texas A&M Univer…
☐	4	University of Texas…
☐	4	Planet Biotechnolo…
☐	4	Johns Hopkins Uni…
☐	4	Wadsworth Center



Stemmy was program lead on 20-29 grants annually from 2013-2019, then suddenly in 2020 that jumped over double the usual to 69 grants

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☐	3	Colorado State Uni…
☐	3	University of Florida

https://www.nature.com/articles/s41579-018-0118-9

nature reviews microbiology

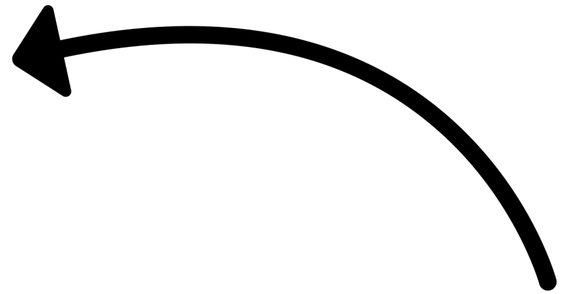
Review Article | Published: 10 December 2018

Origin and evolution of pathogenic coronaviruses

Jie Cui, Fang Li & Zheng-Li Shi ✉

Nature Reviews Microbiology **17**, 181–192 (2019) | Cite this article

371k Accesses | **3254** Citations | **1509** Altmetric | Metrics



Fang Li & the “bat Lady” Zheng-Li Shi
December 2018

Abstract

Severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are two highly transmissible and

- From: "David Morens" [redacted]@gmail.com>
  Sent: 7/13/2020 9:21:23 PM +0000
  To: "Keusch, Gerald T" [redacted]@bu.edu>
  CC: Peter Daszak [redacted]@ecohealthalliance.org>
  Subject: Re: PRO/AH/EDR> COVID-19 update (312): China, SARS-CoV2 origin, animal reservoir, WHO mission

- From: "David Morens" [redacted]@gmail.com>
  Sent: 4/26/2020 9:29:26 PM +0000
  To: "Keusch, Gerald T" [redacted]@bu.edu>
  CC: Peter Daszak [redacted]@ecohealthalliance.org>; Aleksei Chmura [redacted]@ecohealthalliance.org>
  Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Erik Stemmy was the Program Officer for AI110964

EcoHealth ALliance

Funding Agency

Agency	National Institute of Health (NIH)	Project Start	2014-06-01
Institute	National Institute of Allergy and Infectious Diseases (NIAID)	Project End	2020-04-24
		Budget Start	2019-07-24
Type	Research Project (R01)	Budget End	2020-04-24
Project #	2R01AI110964-06	Support Year	6
Application #	9819304	Fiscal Year	2019
Study Section	Clinical Research and Field Studies of Infectious Diseases Study Section (CRFS)	Total Cost	
		Indirect Cost	
Program Officer	Stemmy, Erik J		

Institution

Name	Ecohealth Alliance, Inc.	City	New York
Department		State	NY
Type		Country	United States
DUNS #	077090066	Zip Code	10001

T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
RBD recombinant protein-based SARS vaccine for biodefense								
5 R01AI098775-02			HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	$1,085,321
Epidemiology and modeling of the population dynamics of influenza and antimicrobi								
5 K01AI101010-02			GOLDSTEIN, EDWARD	HARVARD SCHOOL OF PUBLIC HEALTH	2013	NIAID	NIAID	$126,873
RBD recombinant protein-based SARS vaccine for biodefense								
3 R01AI098775-02S1			HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	$3,936
Mechanisms of viral proteases in coronavirus replication and pathogenesis								
5 R01AI085089-04			BAKER, SUSAN C. MESECAR, ANDREW D	LOYOLA UNIVERSITY CHICAGO	2013	NIAID	NIAID	$712,986
Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis								
5 R01AI095569-03			FRIEMAN, MATTHEW BRYAN	UNIVERSITY OF MARYLAND BALTIMORE	2013	NIAID	NIAID	$485,623
Epidemiology, transmission, and phylogenetics of influenza in a tropical country								
5 U01AI088654-04			HARRIS, EVA GORDON, AUBREE L	UNIVERSITY OF CALIFORNIA BERKELEY	2013	NIAID	NIAID	$702,118
Analysis of Coronavirus-Host Cell Interactions								
5 R01AI099107-02			MAKINO, SHINJI	UNIVERSITY OF TEXAS MED BR GALVESTON	2013	NIAID	NIAID	$359,550

Receptor recognition mechanisms of coronaviruses						
5 R01 AI089728-04	LI, FANG	UNIVERSITY OF MINNESOTA	2013	NIAID	NIAID	$351,302
Structure and Mechanism of Programmed Ribosomal Frameshifting in SARS coronavirus						
1 R01 AI104711-01	D'SOUZA, VICTORIA MANUEL	HARVARD UNIVERSITY	2013	NIAID	NIAID	$357,435
Determinants of Coronavirus Fidelity in Replication and Pathogenesis						
1 R01 AI108197-01	DENISON, MARK R BARIC, RALPH S	VANDERBILT UNIVERSITY	2013	NIAID	NIAID	$560,000
PPG: SARS-CoV-host cell interactions and vaccine development						
5 P01 AI060699-08	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2013	NIAID	NIAID	$1,605,748
Evaluation of SARS-CoV 2'O Methyltransferase Mutants						
1 F32 AI102561-01A1	MENACHERY, VINEET D	UNIV OF NORTH CAROLINA CHAPEL HILL	2013	NIAID	NIAID	$52,190
Role of anti-SARS-CoV T cell response in pathogenesis						
5 R01 AI091322-03	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2013	NIAID	NIAID	$354,850
Broad Spectrum Neutralizing Human Abs to SARS and Related Coronaviruses						
5 R01 AI085524-04	MARASCO, WAYNE A.	DANA-FARBER CANCER INST	2013	NIAID	NIAID	$1,025,389
Mechanisms of viral proteases in coronavirus replication and pathogenesis						
5 R01 AI085089-05	BAKER, SUSAN C. MESECAR, ANDREW D	LOYOLA UNIVERSITY CHICAGO	2014	NIAID	NIAID	$602,456

Understanding the Risk of Bat Coronavirus Emergence						
1 R01AI110964-01	DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2014	NIAID	NIAID	$666,442
Role of anti-SARS-CoV T cell response in pathogenesis						
5 R01AI091322-04	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2014	NIAID	NIAID	$377,500
Receptor recognition mechanisms of coronaviruses						
5 R01AI089728-05	LI, FANG	UNIVERSITY OF MINNESOTA	2014	NIAID	NIAID	$373,725
RBD recombinant protein-based SARS vaccine for biodefense						
5 R01AI098775-03	HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	$1,134,359
Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis						
5 R01AI095569-04	FRIEMAN, MATTHEW BRYAN	UNIVERSITY OF MARYLAND BALTIMORE	2014	NIAID	NIAID	$528,500
Analysis of Coronavirus-Host Cell Interactions						
3 R01AI099107-03S1	MAKINO, SHINJI	UNIVERSITY OF TEXAS MED BR GALVESTON	2014	NIAID	NIAID	$30,327
RBD recombinant protein-based SARS vaccine for biodefense						
3 R01AI098775-03S1	HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	$3,936
Deciphering the Role of the Coronavirus Macro Domain in SARS-CoV Infection						
1 F32AI113973-01	FEHR, ANTHONY R	UNIVERSITY OF IOWA	2014	NIAID	NIAID	$53,282



Martin Friede, Ph.D.
Coordinator, Initiative for Vaccine Research at the World Health Organization
(mSAC Chair)



Dr. Danilo Casimiro, Ph.D.
Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines



Barney Graham, M.D., Ph.D.
Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis Laboratory.



Drew Weissman, M.D., Ph .D.
MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core Director of Vaccine Research, Infectious Diseases Division



Duccio Medini, Ph.D.
R3 Program Director at Wellcome Leap, global ARPA for Health, and Strategic Data Science Director at Toscana Life Sciences Foundation, Siena (Italy).



Dr. Connie Schmaljohn
Director, NIAID Integrated Research Facility (IRF-Frederick)



Suhaib Siddiqui, Ph.D.
Former director of chemistry at Moderna Founder of Antirna Inc



Kiat Ruxrungtham, M.D.
Professor of Medicine, Department of Medicine Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center

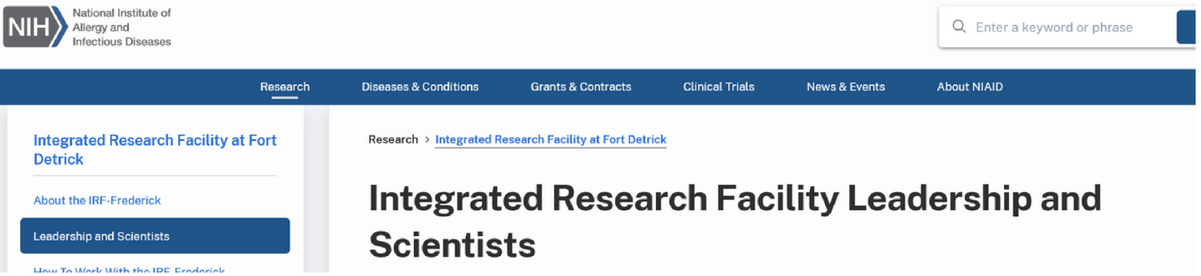
USAMRIID/IRF at NIH, Awarded by the US ARMY

Director at Moderna

Vanderbilt NIH's VRC

UPenn Nobel Winner for mRNA

https://medicinespatentpool.org/who-we-are/governance-teams#Advisory-Panels/



https://www.niaid.nih.gov/research/integrated-research-facility-leadership-scientists

IRF-Frederick Leadership

Connie Schmaljohn, Ph.D.

Director, Integrated Research Facility at Fort Detrick

Contracting Officer's Representative (COR)

Contact: For contact information, search the NIH Enterprise Directory.

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a...



Biography

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a Ph.D. in virology from Colorado State University, after which she joined USAMRIID as a National Research Council postdoctoral fellow. Her subsequent positions at USAMRIID included Principal Investigator as well as Chief, Molecular Virology Branch. Dr. Schmaljohn's research background is in molecular virology and molecular vaccine development. She has served as president of the International Society of Hantaviruses, chair of the American Society for Microbiology Biodefense Conference, and chair of the International Committee on the Taxonomy of Viruses *Bunyaviridae* Study Group. She also has served on the Interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Viral Hemorrhagic Fevers Integrated Product Team (IPT), the Board of Scientific Counselors for the NIAID Vaccine Research Center, and the Scientific Advisory Council for the Coalition of Emergency Preparedness Innovations (CEPI). She was elected to the American Academy of Microbiology (2007) and was selected as fellow of the International Society for Vaccines (2015). She received the Order of Military Merit (2002), the Association of Military Surgeons of the United States Research Award (2002), the University of Nebraska Alumni Achievement Award (2012), and the Presidential Rank Award (2017).

U.S. ARMY



Dr. Connie S. Schmaljohn of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has been awarded the Meritorious Senior Professional Rank Award for the Department of the Army for 2017.

Schmaljohn is Senior Research Scientist for Medical Defense Against Infectious Disease Threats (ST) at USAMRIID and her research involves developing medical countermeasures against highly lethal viruses of military importance. She was instrumental in the discovery of hantaviruses, a previously unknown class of rodent-borne viruses that cause hemorrhagic fever or severe respiratory

U.S. ARMY

https://www.army.mil/article/210940/usamriids_schmaljohn_receives_presidential_rank_award

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Therapure Biomanufacturing Signs Manufacturing Deal With VBI Vaccines for Coronavirus Vaccine Candidates

August 18, 2020 09:04 AM Eastern Daylight Time

MISSISSAUGA, Ontario--(BUSINESS WIRE)--Therapure Biomanufacturing, a division of Therapure Biopharma Inc., announced today the signing of an agreement with VBI Vaccines Inc. for the manufacture of their coronavirus vaccine candidates. Therapure Biomanufacturing is an integrated contract development and manufacturing organization (CDMO) focused on biologic and high value therapeutics that can provide new options for patient care. Under this agreement, Therapure will be responsible for the biomanufacturing of the vaccine drug substance as well as the aseptic fill of the drug product at the Therapure facility in Mississauga, Ontario.

Mr. Safa'a Al-Rais, Therapure's Chief Operating Officer, said: "We are delighted to partner with VBI to assist with providing an effective response to the ongoing COVID-19 pandemic through Therapure's biomanufacturing and aseptic fill finish services for VBI's innovative COVID-19 vaccine candidates, which utilize their flexible enveloped virus-like particle (eVLP) platform technology. Therapure prides itself on its development, clinical and commercial cGMP manufacturing expertise providing solutions for biologic therapeutics and innovative drug delivery technologies, which make a difference in patients' lives."

"We look forward to working with Therapure to address the ongoing public health challenge," said Jeff Baxter, VBI's President and CEO. "Therapure's proven cGMP biomanufacturing capabilities and expertise with aseptic fill finish make them a great partner as we advance our vaccine candidate into and through clinical studies."

ABOUT THERAPURE BIOMANUFACTURING

Therapure Biomanufacturing is the award-winning contract development and manufacturing division of Therapure Biopharma Inc. offering integrated services for developing, manufacturing, purifying and packaging complex biological therapeutics and technologies. Our scientific and manufacturing expertise, as well as our flexible state-of-the-art facility with a successful regulatory track record including an FDA approval for commercial manufacturing, provides clients with optimal biomanufacturing solutions to advance their

https://www.businesswire.com/news/home/20200818005214/en/Therapure-Biomanufacturing-Signs-Manufacturing-Deal-VBI-Vaccines

https://www.vbivaccines.com/press-releases/cepi-collaboration/

VBI VACCINES

Coronavirus | Press Releases

CEPI and VBI Vaccines Collaborate to Advance Vaccine Candidates Against COVID-19 Variants

March 10, 2021

- *Up to $33m of funding will support development of VBI's enveloped virus-like particle (eVLP) vaccine candidates against COVID-19 variants of concern.*
- *Phase 1 clinical study of VBI's eVLP vaccine candidate, VBI-2905, targeting the B.1.351 variant, anticipated to initiate mid-year 2021.*

CEPI, the Coalition for Epidemic Preparedness Innovations, and VBI Vaccines Inc. (Nasdaq: VBIV), today announced a partnership to

VBI VACCINES

Commercial Advisory Board

Management Team | Board of Directors | Scientific and Clinical Advisory Boards | Commercial Advisory Board

Meet Our Commercial Advisors

This Board, comprised of public health policy, epidemiology, and vaccine development experts, works closely with our management team to provide guidance for the pre-launch and commercialization strategy of our pipeline programs.

Damian Braga
Director, Chair of Commercial Advisory Board

United States

Eddy A. Bresnitz, M.D., M.S.C.E.

Michael D. Decker, M.D., M.P.H.

John D. Grabenstein, Ph.D., R.Ph.

Eddy A. Breshitz, M.D., M.S.C.E.

Michael D. Decker, M.D., M.P.H.

John D. Grabenstein, Ph.D., R.Ph.

Michael D. Decker, M.D., M.P.H.

Current Adjunct Professor of Preventive Medicine at Vanderbilt University Medical Center, Dr. Decker is a well-published expert on vaccines, preventive medicine, and public health policy. In 2016, Dr. Decker retired from Sanofi Pasteur after more than 15 years, where he was Vice President and Global Medical Expert from 2013-2016 and Vice President, Scientific and Medical Affairs, and Chief Medical Officer, Sanofi Pasteur U.S., from 2000-2012. From 1984-2000, Dr. Decker was a Professor of Preventive Medicine and Medicine (Infectious Diseases) at Vanderbilt University School of Medicine. He has also previously served as a Medical Officer in the U.S. Public Health Service at the Centers for Disease Control and Prevention (CDC), as Editor-in-Chief of the journal Infection Control and Hospital Epidemiology from 1993 to 2001, and as Co-Editor of the International Journal of Health Governance from 2016 to 2020.

< Sanofi, CDC, Vanderbilt



David E. Anderson, Ph.D.

Chief Scientific Officer

A dynamic and well-published immunologist with broad expertise in the areas of vaccine development, autoimmunity and tumor immunology, Dr. Anderson joined VBI full time in 2009 from Harvard Medical School, where he held a position as Assistant Professor. As a co-founder and Chief Scientific Officer of VBI, Dr. Anderson is an inventor of much of the Company's intellectual property and actively manages its ongoing expansion. Dr. Anderson holds a Ph.D. from Harvard University and a B.S. from the University of California at Davis.

Harvard + UC Davis>

Scientific and Clinical Advisory Boards

Meet Our Scientific and Clinical Advisors

These highly-regarded global experts in infectious disease, immuno-oncology, and vaccine development help guide the advancement and direction of our pipeline programs.

Michel De Wilde, Ph.D.
Director, Chair of Scientific and Clinical Advisory Boards

Hepatitis B Virus (HBV)

Adam Finn, M.D., Ph.D.

Peter A. Patriarca, M.D.

Daniel Shouval, M.D.

Bruce Smith, Ph.D.

Stefan Thoelen, M.D.

Pierre Van Damme, M.D., Ph.D.

Glioblastoma (GBM)

Denis R. Burger, Ph.D.

Michael Lim, M.D.

Allen Waziri, M.D.

Patrick Yung Wen, M.D.

Cytomegalovirus (CMV)

Robert Pass, M.D.

Stanley Plotkin, M.D.

VBI VACCINES

Eddy A. Bresnitz, M.D., M.S.C.E.

John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

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Our Focus
Our Science
Our Pipeline
Clinical Trials
Investors
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Steven Gillis, Ph.D.

Chairman of the Board

Steven Gillis, Ph.D., has been a Managing Director of ARCH Venture Partners since 2006 and joined the firm in 2005. Dr. Gillis is focused on the evaluation of new life science technologies and also on the development and growth of ARCH's biotechnology portfolio companies. He is a director of Takeda Pharmaceutical Co. Ltd. (TAK), Homology Medicines, Inc. (FIXX), and also serves as Chairman of Codiak Biosciences (CDAK). Dr. Gillis represents ARCH as a managing director and serves as Chairman of a number of ARCH's private, biotechnology portfolio companies.

Dr. Gillis was a founder and director of Corixa Corporation and served as CEO from its inception and as its Chairman from 1999 until its acquisition in 2005 by GlaxoSmithKline. Prior to Corixa, Dr. Gillis was a founder and director of Immunex Corp. From 1981 until his departure in 1994, Dr. Gillis served as Immunex's Director of Research and Development, Chief Scientific Officer, and as CEO of Immunex's R&D subsidiary. Dr. Gillis was interim CEO of Immunex Corp. following its majority purchase by American Cyanamid Company and remained a member of the board until 1997. Amgen, Inc. acquired Immunex in 2002.

Dr. Gillis is an immunologist by training with over 300 peer-reviewed publications in the areas of molecular and tumor immunology. He is credited as being a pioneer in the field of cytokines and cytokine receptors, directing the development of multiple marketed products including Leukine, (GM-CSF), Prokine (IL-2) and Enbrel (soluble TNF receptor-Fc fusion protein) as well as the regulatory approval of Bexxar (radiolabeled anti-CD20). Dr. Gillis received a B.A. from Williams College and a Ph.D. from Dartmouth College.

< ARCH VENTURES
Takeda
GSK
Immunex
[prior to acquisition by Amgen,]
DARTHMOUTH

Michel De Wilde, Ph.D.

Director

Michel De Wilde, Ph.D., was Senior Vice President, Research & Development, at Sanofi Pasteur, the human vaccines division of Sanofi from 2001 until June 2013. In this position, he was responsible for managing approximately 1,500 employees and a broad portfolio of approximately 20 development projects.

Prior to joining Sanofi Pasteur in January 2000, Dr. De Wilde was at SmithKline Beecham Biologicals (now GSK Vaccines) in Rixensart, Belgium. Dr. De Wilde joined the group in 1978 as a research scientist upon formation of a unit focusing on the application of recombinant DNA technology to vaccine development. He subsequently held positions of increasing responsibility and, as Vice President, Research & Development at Sanofi Pasteur, headed a team of approximately 400 specialists, active in all aspects of preclinical vaccine development.

Dr. De Wilde a member of a number of Scientific Advisory Boards, including COVAX Independent Product Group and other COVID related advisory bodies.

Dr. De Wilde received his degree in Chemistry from the Free University of Brussels in 1971, followed by a Ph.D. in Biochemistry in 1976. He carried out postdoctoral work at the University of Wisconsin, Madison (U.S.) and the University of Ghent (Belgium). Dr. De Wilde authored over 50 publications during the early part of his career.

^Sanofi, GSK, COVAX, University of Wisconsin Madison

VBI VACCINES

John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

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Our Partnerships and Collaborations

Brii Biosciences (Brii Bio)

VBI and Brii Bio have a license and collaboration agreement for the development of VBI-2601 (BRII-179) as part of a potential functional cure for chronic hepatitis B infection.

Read Press Release

Government of Canada

Through their Strategic Innovation Fund, the Government of Canada awarded VBI up to a CAD $56 million contribution to support the development of the Company's prophylactic coronavirus vaccine candidates, VBI-2901 and VBI-2902, through Phase 2 clinical studies.

Coalition for Epidemic Preparedness Innovations (CEPI)

As part of their collaboration, CEPI will provide VBI up to $33M of funding to support development of VBI's eVLP vaccine candidates against COVID-19 variants of concern, including B.1.351, the variant first identified in South Africa.

Read Press Release

GlaxoSmithKline (GSK)

VBI and GSK have a collaboration to clinically evaluate the combination of VBI-1901, VBI's cancer vaccine immunotherapeutic candidate, with GSK's proprietary AS01 adjuvant system in patients with recurrent glioblastoma (GBM).

Read Press Release

Resilience Biotechnologies, Inc. (Resilience)
(previously Therapure Biopharma Inc.)

VBI and Resilience have an agreement for the development and manufacturing services in preparation for production of its coronavirus vaccine candidates. The collaboration is expected to support clinical studies through Phase 2 clinical development.

Syneos Health (Syneos)

VBI and Syneos Health have a partnership for commercialization of VBI's prophylactic hepatitis B program.

Read Press Release

Individual Members – Join or Renew Now!
Organizational Members – Join or Renew Now!
Pharmacy Education Fund – Contribute Now!
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Sponsorship



President (Term: 2022-2024)
John D. Grabenstein, RPh, PhD, ScD (Hon), is a globally recognized vaccinologist, pharmac
300 articles and 11 books, primarily on topics of immunization, public health, and leadershi
a consultancy providing services related to human vaccines, antibody products, and other immunologic drugs. He also serves as the Managing Editor of *IZ Express*, the newsletter of Immune.org.

Dr. Grabenstein received his pharmacy degree from Duquesne University, a master's degree in education from Boston University, and a doctorate in epidemiology at the University of North Carolina. He was elected to the National Academy of Medicine in 2021 and is a Fellow of the Royal Society for Public Health. Dr. Grabenstein is the 2020 recipient of APhA's Remington Honor Medal, American pharmacy's highest honor for distinguished service. An AIHP member since 1994, Dr. Grabenstein joined the Institute's Board of Directors in 2018, served as Vice President from 2020-21, and became the organization's President in November 2021.

Dr. Grabenstein's prior positions include Global Director of Medical Affairs for Merck Vaccines (where he led medical-affairs and scientific-policy activities for a global enterprise that provided 180 million doses annually for 13 vaccines) and Director of the U.S. Department of Defense's Military Vaccine Agency (where he oversaw the Defense Department immunization programs for 9 million troops, retirees, and family members spread across four continents and dozens of ships at sea).

https://aihp.org/about/aihp-board-of-directors/

From: Peter Daszak
Sent: Tuesday, April 28, 2020 11:30 AM
To: 'Hongying Li' <li@ecohealthalliance.org>; Tammie O'Rourke <torourke@metabiota.com>
Cc: Goldstein, Tracey <tgoldstein@ucdavis.edu>; Aleksei Chmura <chmura@ecohealthalliance.org>; Christine Kreuder Johnson <ckjohnson@ucdavis.edu>
Subject: RE: China Genbank Sequences
Importance: High

All – It's extremely important that we don't have these sequences as part of our PREDICT release to Genbank at this point.

As you may have heard, these were part of a grant just terminated by NIH.

https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076

Having them as part of PREDICT will being very unwelcome attention to UC Davis, PREDICT and USAID.

Cheers,

Peter

This email from Daszak was sent out to EHA and Metabiota staff urging them not to publish Viral Sequences to Genbank for fear it would bring "very unwelcome attention to UC Davis, PREDICT and USAID"

USAID is a CIA front. The CIA's investment arm, In-Q-Tel is a major funder of Hunter Biden's failed Metabiota.

This email occurred 3 weeks BEFORE EHA & Wuhan decided to upload SHC014 [Close chimeric relative to SARS2] to Genbank after 5 years! [May 22 2020]

https://sciencex.com/wire-news/56829642/dana-farber-receive-56-million-grant-to-develop-rapid-countermea.html

This Science News Wire page contains a press release issued by an organization and is provided to you **"as is"** with little or no review from Science X staff.

Dana-Farber receive $5.6 million grant to develop rapid countermeasures to infectious agents

January 18th, 2011

BOSTON--Researchers at Dana-Farber Cancer Institute have received a $5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

Wayne Marasco of the NIH's Vaccine Research Center working with in 2011 DARPA for;

"This grant will support revolutionary advances in rapid response to naturally evolving AND ENGINEERED PATHOGENS."

BOSTON--Researchers at Dana-Farber Cancer Institute have received a $5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

Wayne A. Marasco, MD, PhD, of the Department of Cancer Immunology and AIDS at Dana-Farber and an associate professor of Medicine at Harvard Medical School, is the project's principal investigator.

Since the mid 1990's, DARPA's Defense Sciences Office has pioneered advances across the full spectrum of bio-warfare defense needs, including the development of advanced diagnostics and medical therapies that are active against an entire range of infectious agents.

"This grant will support revolutionary advances in rapid response to naturally evolving and engineered pathogens," says Marasco. "DARPA has issued a challenge to develop a treatment to unknown threats in just seven days, and we are excited about the opportunity to meet this challenge."

ELSEVIER

Journal of Immunological Methods 246 (2000) 97–108

JIM
Journal of Immunological Methods

www.elsevier.nl/locate/jim

Expression of a human, neutralizing monoclonal antibody specific to Puumala virus G2-protein in stably-transformed insect cells

Mary C. Guttieri*, Carol Bookwalter, Connie Schmaljohn

Virology Division, United States Army Medical Research Institute of Infectious Diseases, Bldg. 1301, Fort Detrick, Frederick, MD 21702-5011, USA

Received 29 May 2000; received in revised form 12 September 2000; accepted 13 September 2000

Strange how Metabiota's Guttieri collaborated with USAMRIID/IRFs Schmaljohn on Monoclonal Antibodies at Fort Detrick in 2000

https://www.uvm.edu/~cbookwal/296c/guttieri.pdf

Therapure Biopharma Awarded US Government Contract

News Published: June 20, 2013

Therapure Biopharma Inc. has announced the company will participate as a subcontractor for DynPort Vaccine Company LLC (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of $157.3 million (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

https://www.technologynetworks.com/drug-discovery/news/therapure-biopharma-awarded-us-government-contract-211685

1

https://www.pharmaceutical-technology.com/contractors/contract-manufacturers/therapure-biopharma/pressreleases/presstherapure-biopharma-awarded-us-government-contract-for-development-of-anti-nerve-gas-agent/

Therapure Biopharma

Therapure Biopharma Awarded US Government Contract for Development of Anti-Nerve Gas Agent

Make an enquiry

Therapure Biopharma, a contract development and manufacturing organization (CDMO) of biotherapeutics, is pleased to announce that the company will participate as a subcontractor for DynPort Vaccine Company (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of $157.3m (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

Therapure's subcontract under the above prime contract includes process optimization as well as manufacture of all clinical and nonclinical materials (drug product) to support DVC's contract to develop, test and obtain the US Food and Drug Administration (FDA) approval for human plasma-derived butyrylcholinesterase (HuBChE), a blood plasma protein that binds and inactivates nerve agents. Mr Nick Green, therapure's president and chief executive officer, said; "We are delighted to partner with DVC to develop and manufacture medical counter measures for the US Department of Defense as part of a defense strategy against a wide range of nerve gases. Therapure successfully completed a rigorous selection and approval process to serve as the manufacturing subcontractor under the prime contract, which is a testament to the company's standards and capabilities in biomanufacturing. It is an honor to be part of this very critical initiative to protect US Servicemen and women."

Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the US Department of Defense, Department of the Army, Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO), Medical Identification and Treatment Systems Joint Product Management Office (MITS JPMO).


DEPARTMENT
of
DISTRESS

OPERATION WARP SPEED [OWS]

Operation Warp Speed



Official seal of Operation Warp Speed

Active	May 15, 2020 – February 24, 2021 (285 days)
Disbanded	Transitioned to White House COVID-19 Response Team
Country	United States
Allegiance	United States
Part of	U.S. Department of Defense U.S. Department of Health and Human Services Other various government agencies

According to the search results, the 8 companies that received funding of around $11 billion from Operation Warp Speed as of August 2020 to expedite development and preparation for manufacturing their COVID-19 vaccine candidates were:

1. Johnson & Johnson (Janssen Pharmaceutical) - $1 billion
2. AstraZeneca–University of Oxford and Vaccitech - $1.2 billion
3. Moderna - $1.5 billion
4. Novavax - $1.6 billion
5. Pfizer & BioNTech - $1.95 billion
6. Sanofi & GlaxoSmithKline - $2.1 billion
7. Regeneron - $450 million
8. Emergent BioSolutions - $628 million

The search results provide a comprehensive list of the 8 companies that received significant funding from Operation Warp Speed to accelerate the development and manufacturing of their COVID-19 vaccine candidates as of August 2020. [1] [3] [4]

DoD + HHS

In total 8 companies were backed by OWS

OWS MCM Enterprise & Responsible Participants

OWS Injectables, therapies & other biological MCMs			
Drug Name(s):	**Manufacturers:**	**Market Status:**	**Involved Government Affiliations & Agencies:**
Remdesivir/Veklury	Gilead+ Ligand Pharmaceuticals	1st Use May 2020, Full Approval Oct 2020 All ages by April 2022	USAMRIID, NIH, UNC Chapel Hill, Univ AL, Vanderbilt, Columbia, DTRA, JSTO-CBD, DARPA
Lagevrio/ Molnupiravir	Merck +Ridgeback Bio	First Authorization Dec 2021	Emory DRIVE LLC
Paxlovid/ niratrelvir+ritonavir	Pfizer	Full Approval May 2023 First Use Dec 2021	
Bamlanivimab/LY-CoV555	Abcellera +Eli Lily	EUA Nov 2020,Renewed March 2021 Revoked April 2021	BMGF + DARPA's P3 Program [ADEPT]
Bebtelovimab	Abcellera +Eli Lily	EUA Feb 2022	Bill & Melinda Gates Foundation

Educational Institutions

Vanderbilt
UNC Chapel Hill
Univ. Penn
Univ TX Med Branch
Dartmouth
Emory
Univ. Alabama
Johns Hopkins
Georgetown

Non-Government Organizations

Bill & Melinda Gates Foundation [BMGF]
Scripps
CEPI
Wellcome Trust
EcoHealth Alliance
In-Q-Tel

Governmental Organizations

JPEO-CBRN [ARMY]
NIH/NIAID/FNIH
DARPA
DTRA
BARDA
ASPR/HHS
NSF
DHS-CWMD

OWS Funded MCMs

1. **AstraZeneca —** In May, AstraZeneca signed a contract for $1.2 billion to boost access to its COVID-19 vaccine. In October, the drugmaker signed a second contract for $486 million for the U.S. to secure 100,000 doses of its experimental COVID-19 antibody drug and support clinical trials for the drug.

2. **Cytiva —** The Massachusetts drugmaker signed a contract in October for $31 million to scale up production of materials needed to produce COVID-19 vaccines, such as liquid and dry powder cell culture media, cell culture buffers, bioreactors and mixer bags.

3. **Eli Lilly —** In October, Eli Lilly signed a $375 million contract to supply 300,000 vials of its COVID-19 antibody drug, which was granted emergency authorization by the FDA in November. In early December, the drugmaker signed another $812.5 million contract to supply 650,00 more doses of the drug.

4. **Emergent BioSolutions —** In June, Emergent BioSolutions signed a $628 million contract to ramp up its contract development and manufacturing capabilities to expedite the delivery of COVID-19 vaccines.

5. **Fujifilm —** In July, Fujifilm signed a $265 million contract to manufacture COVID-19 vaccines.

6. **Johnson & Johnson —** In August, Johnson & Johnson signed a more than $1 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine if it is authorized.

HTTPS://WWW.BECKERSHOSPITALREVIEW.COM/PHARMACY/13-DRUGMAKERS-CONTRACTED-BY-OPERATION-WARP-SPEED-IN-2020.HTML

7. **Moderna —** In August, Moderna signed a $1.5 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

8. **Novavax —** In July, Novavax signed a $1.6 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

9. **Pfizer & BioNTech —** In July, Pfizer and BioNTech partnered to sign a $1.95 billion contract to supply up to 600 million doses of its COVID-19 vaccine. Under the contract, the U.S. would receive 100 million doses of the vaccine with the opportunity to secure 500 million more doses, but the U.S. did not secure the additional doses.

10. **Regeneron —** In July, Regeneron signed a $450 million contract to manufacture thousands of doses of its COVID-19 antibody cocktail, which was granted emergency authorization in November.

11. **Sanofi & GlaxoSmithKline —** In July, Sanofi and GlaxoSmithKline partnered to sign a $2.1 billion contract for development of the drugmaker's COVID-19 vaccine as well as an initial supply of 100 million doses.

ADEPT : PROTECT

THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses

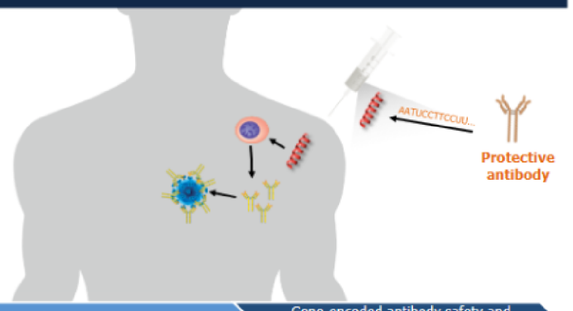
THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

P3

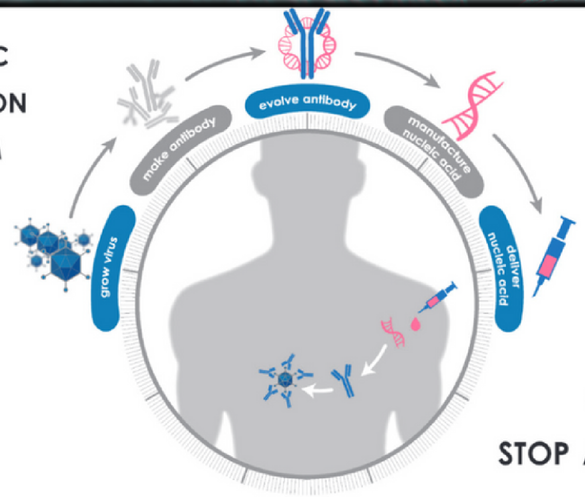
DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

Gene-encoded antibodies
for near-immediate, temporary protection
(ADEPT-PROTECT)



Proof-of-concept in animal models (6.1)	Pre-clinical studies & GMP manufacture (6.1 to 6.2)	Gene-encoded antibody safety and expression study in humans (performer funded)
2013-2016	2017-2018	2018-2020

PANDEMIC PREVENTION PLATFORM (P3)



60 DAYS TO STOP A PANDEMIC

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

https://www.darpa.mil/attachments/ADEPTVignetteFINAL.pdf

ADEPT : PROTECT



THE NEED AND OPPORTUNITY

A primary objective of DARPA's Biological Technologies Office (BTO) is to better ensure the health, and thereby the force readiness, of the country's military service community. The COVID-19 pandemic, which rapidly spread worldwide from an initial outbreak in China at the end of 2019, highlights one of the most perilous vulnerabilities to deployed military personnel and civilians: lack of protection and medical countermeasures (MCMs) against endemic and emerging biothreats. The Zika outbreak in 2015-2016, the more recent Ebola outbreak in the Democratic Republic of Congo, and mosquito-borne viruses such as Chikungunya and Dengue are among these threats.

Vaccines are the traditional mainstay of long-term infection prevention, while antibody approaches have at times been used to treat active infections. In one antibody-based approach that is being applied on a small scale in the current pandemic, blood serum with presumably protective antibodies obtained from those who have recovered from an infection is infused into patients. In more recent decades, monoclonal antibodies manufactured in cultured immune-system cells have been used to treat certain cancers and immune disorders. However, these treatments have suffered from shortcomings – including slow development, expensive manufacture, and dependence on continuous cold storage – that have prevented widespread use by the military.

THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses like the one (SARS-CoV-2) that causes COVID-19, are delivered directly to a recipient's body. There, the instructions carried in the DNA or RNA elicit the body's own cells to manufacture the antigenic viral protein, which, in turn, elicits an immune response to the virus.

Gene-based vaccines have shown great promise as a means to provide safe, reproducible, long-term immune protection. For vaccines to work, however, they often require more than one dose and it often takes weeks to months before a recipient's immune system builds up sufficient protection again the vaccine's viral target. With these biomedical realities come threats to warfighters if they deploy to pathogen-rife regions before having established relevant immunity and threats to military missions due to delayed deployment of personnel until they achieve immune protection.

For a vaccine to confer immunity, it must lead to the production within a recipient of highly potent antibodies that can neutralize the pathogen. DARPA initiated the ADEPT:PROTECT program (most often referred to more simply as ADEPT) with the intention of bushwhacking a novel pathway to near-immediate protection against pathogens for which vaccines are not yet available and to confer interim-term protection during the development of a vaccine, which can take years.

THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

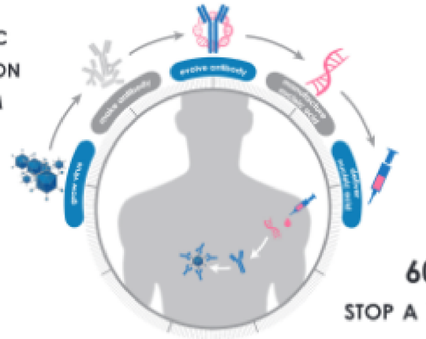
Earlier proof-of-concept experiments funded under ADEPT primarily with 6.1 funding (for basic research) demonstrated that delivery of antibody-making instructions — by way of messenger ribonucleic acid (mRNA), deoxyribonucleic acid (DNA), or another genetic-information-carrying tactic that relies on small viruses known as adenovirus-associated viruses (AAVs) — led to the production of antibodies that conferred protection in test animals exposed to the mosquito-borne Chikungunya (ChikV) virus.

In a more applied phase of technology development, Moderna was converted to 6.2 funding (applied research) to begin pre-clinical studies in non-human primates with an RNA-encoded antibody against ChikV and to produce the countermeasure using Good Manufacturing Practices (GMP), which regulatory agencies such as the Food and Drug Administration often require.

Moderna subsequently used company funding to conduct a Phase I clinical trial with 22 healthy volunteers using an mRNA-encoded ChikV antibody. This marked the first safety demonstration of an RNA-based medical countermeasure. Moderna reported these promising results of its clinical study in 2019. The trial demonstrated platform safety as well as the ability to generate protective levels of functional antibody in humans. In response to COVID-19, Moderna in March 2020 initiated human trials of gene-encoded antibodies that target SARS-CoV-2.

Research by Moderna and other ADEPT performers has provided proof-of-concept results that simultaneously delivering gene-encoded antibody treatment and vaccine confers the recipient with immediate immune

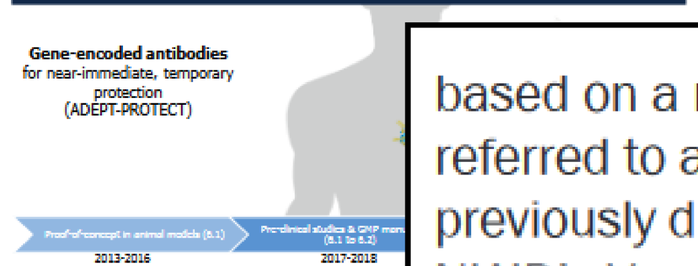
PANDEMIC PREVENTION PLATFORM (P3)



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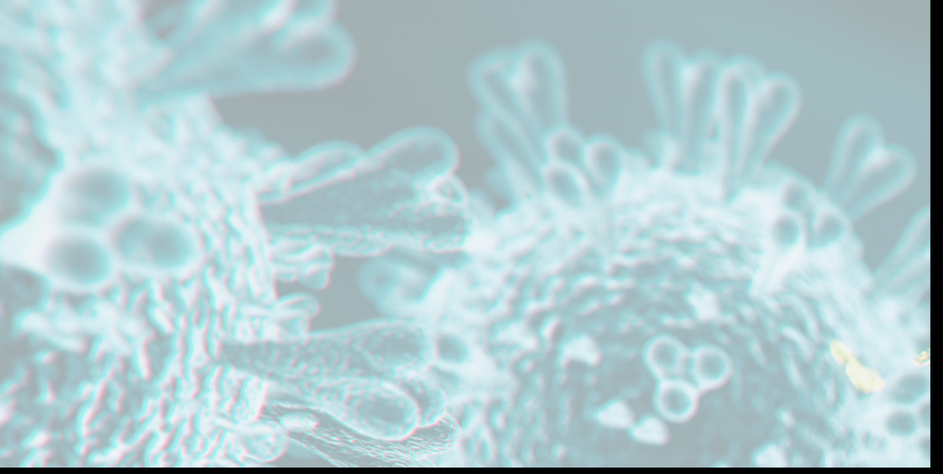
DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats



based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017 Ebola outbreak in the Democratic Republic of Congo, where it conferred significant survival benefits over other EUA-sanctioned Ebola therapeutics. To enable continued availability of mAb-114, DARPA and JPEO-CBRND in 2018 co-funded the manufacture of additional doses at Ology Biosciences through its DoD-funded Advanced Development and Manufacturing (ADM) facility.

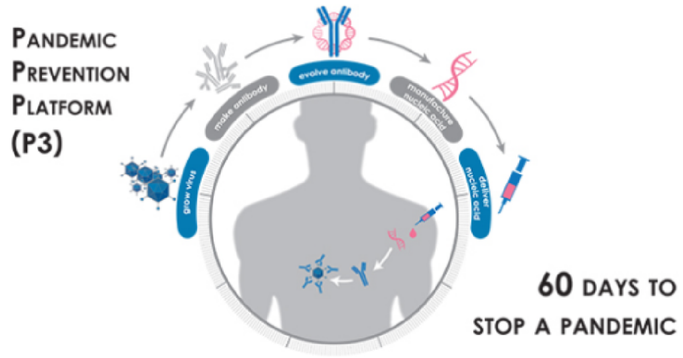
and Contagious Threats (ADEPT: PROTECT)



Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

DARPA aims to develop an integrated end-to-end platform that uses nucleic acid sequences to halt the spread of viral infections in sixty days or less

OUTREACH@DARPA.MIL
2/6/2017



Over the past several years, DARPA-funded researchers have pioneered RNA vaccine technology, a medical countermeasure against infectious diseases that uses coded genetic constructs to stimulate production of viral proteins in the body, which in turn can trigger a protective antibody response. As a follow-on effort, DARPA funded research into genetic constructs that can directly stimulate production of antibodies in the body.[1,2] DARPA is now launching the Pandemic Prevention Platform (P3) program, aimed at developing that foundational work into an entire system capable of halting the spread of any viral disease outbreak before it can escalate to pandemic status. Such a capability would offer a stark contrast to the state of the art for developing and deploying traditional vaccines —a process that does not deliver treatments to patients until months, years, or even decades after a viral threat emerges.

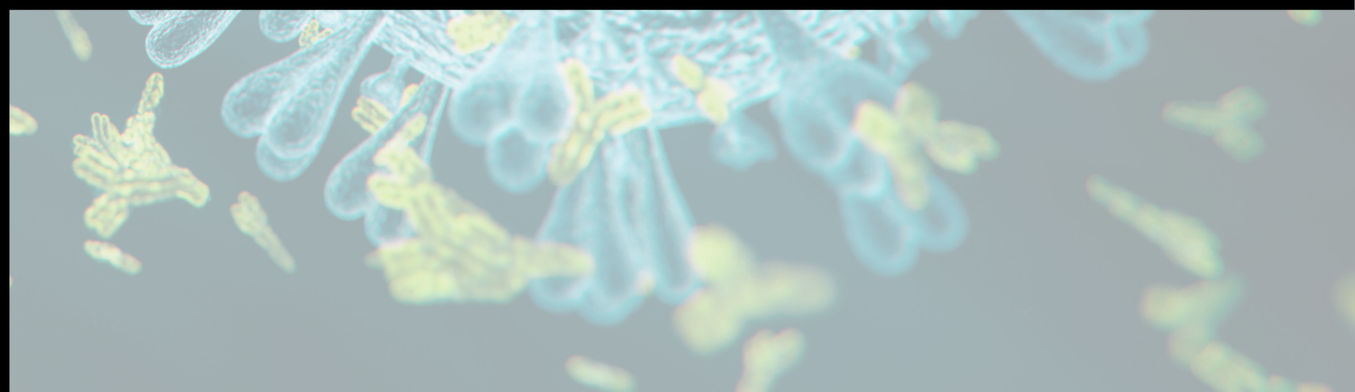
"DARPA's goal is to create a technology platform that can place a protective treatment into health providers' hands within 60 days of a pathogen being identified, and have that treatment induce protection in patients within three days of administration. We need to be able to move at this speed considering how quickly outbreaks can get out of control," said Matt Hepburn, the P3 Program Manager. "The technology needs to work on any viral disease, whether it's one humans have faced before or not."

Col. Matthew Hepburn, M.D.

Center Affiliate

Col. Matthew Hepburn, M.D., is currently assigned to DARPA as a program manager, since 2013. Prior to joining DARPA, Col. Hepburn served as the Director of Medical Preparedness on the White House National Security Staff. Additional previous assignments include: Chief Medical Officer at a Level II medical facility in Iraq, clinical research director at the US Army Medical Research Institute for Infectious Diseases, exchange officer to the United Kingdom and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds Doctor of Medicine and Bachelor of Science in biomedical engineering degrees from Duke University.



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PUBLIC PROCUREMENT AND DISRUPTIVE TECHNOLOGIES: DARPA'S ROLE IN THE DEVELOPMENT OF mRNA VACCINES[1]

Contratación pública y tecnologías disruptivas: el papel de DARPA en el desarrollo de vacunas de ARNm

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RESUMEN: Uno de los propósitos clave del Departamento de Defens
Unidos (DoD) es proporcionar capacidades para ganar la guerra a solc
infantes de marina, aviadores y guardianes. Debido a la naturaleza única
de defensa, esto requiere una constante innovación. Desde la década de
tecnología militar se volvió demasiado sofisticada para los arsenales gu
DoD ha confiado principalmente en contratistas del sector pr
especializados. Sin embargo, para ciertas inversiones en ciencia básic
fallas del mercado, el DoD destina recursos a sus propios esfuerzos d
desarrollo. La institución gubernamental más famosa de estas es la Age
de Investigación Avanzada de Defensa (DARPA), cuyas invencior
aviones furtivos, sistemas de posicionamiento global e internet. Sin
ocurre en la mayoría de los países, una gran parte de la innovación se
privado. Este artículo explora lo que hace excepcional a DARPA, exar
en el desarrollo de tecnologías de ARNm utilizadas posteriormente
vacunas contra el COVID-19. Y advierte que DARPA puede no ser esc

PALABRAS CLAVE: DARPA; tecnologías disruptivas; contratación
mRNA.

ABSTRACT: One of the key purposes of the U.S. Department of Def
deliver war-winning capabilities to soldiers, sailors, marines, airmer
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failures, the DoD devotes resources to its own research and developm
most famous of these government institutions is the Defense Advanced
Agency (DARPA), whose inventions have included stealth aircraft, g

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[2] The opinions expressed here are those of the author and do not necessarily reflect
position of the Department of the Air Force, the Department of Defense, or any other U.S. government agency. This was article was first presented at a virtual conference sponsored by the University of Vigo on 4 October 2021, Temas clave de la contratación pública. The author is grateful to Major Ashley Ruhe, USAF, and to Professor Patricia Valcárcel Fernández, University of Vigo, for valuable contributions

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DARPA's Role in the Development of mRNA Vaccines

Revista de la Escuela Jacobea de Posgrado, Nº 24, junio 2023, págs. 1-16

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Daniel Schoeni
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Date Written: June 26, 2023

Abstract

One of the key purposes of the U.S. Department of Defense (DoD) is to deliver war-winning capabilities to soldiers, sailors, marines, airmen, and guardians. Because of the unique nature of defense procurement, this requires constant innovation. Since the 1950s, when military technology became too sophisticated for government arsenals, the DoD has primarily relied on highly specialized defense contractors in the private sector. However, for certain investments in basic science or to circumvent market failures, the DoD devotes resources to its own research and development efforts. The most famous of these government institutions is the Defense Advanced Research Projects Agency (DARPA), whose inventions have included stealth aircraft, global positioning systems, and the internet. Nevertheless, as in most countries, most innovation occurs in the private sector. This article explores what makes DARPA exceptional, examining its role in the development of mRNA technologies later used to develop COVID-19 vaccines. And it cautions that DARPA may not be scalable.

When Dan Wattendorf arrived at DARPA's biological technologies office in 2010, mRNA technology already existed. The possibility of using the body's own DNA for producing vaccines was recognized as early as 1950. In 2005, Katalin Karikó and Drew Weissman discovered a way to alter mRNA that would increase its therapeutic potential. Wattendorf sought to stimulate research into lipid-based mRNA delivery systems.[17] Even with financial support, large pharmaceutical companies still weren't interested. Wattendorf turned to newer biotech companies, and in 2013 DARPA issued a $25 million grant to a company, which is now a household name: Moderna.[18] As its name would imply (given that the last there letters spell out "RNA" in English), it concentrated on using mRNA to develop human vaccines.[19] By 2019, it had produced the first effective vaccine using mRNA technology.[20] Thus, the fact that DARPA had already made key investments in vaccines pre-COVID underlay the unbelievably rapid pace of OWS.[21]

Apart from its support of mRNA vaccine research a decade before the coronavirus struck, DARPA's organizational structure also served as a model for OWS.[23] OWS was launched on May 15, 2020, and this signaled a partnership between the Department of Health and Human Services, the DoD, and pharmaceutical companies.[24] Several key features of DARPA's structure were incorporated.

DARPA has been credited with several transformative technologies, including ARPANET (the internet), the engines that powered the Apollo missions, GPS, and flat panel displays.[25] One secret of its success lay in doing "connected science". Rather than conducting only basic research, DARPA prides itself in simultaneously mobilizing private-sector production, "enabling full innovation not simply invention."[26] This is a key feature of the DARPA model.

The DARPA model entails several other key elements. First, it is small, composed of only 50–100 program managers.[27] Second, unlike most military organizations, its structure eliminates the typical hierarchy and has only two levels, which fosters cooperation.[28] Third, its technical staff are employed by DARPA for at most 3–5 years, encouraging fresh thinking and reducing careerism.[29] Fourth, it uses a "portfolio approach", funding multiple lines of research in parallel, knowing many of these will surely fail.[30] Last, DARPA utilizes flexible contracting procedures, especially the renowned "Other Transactions Authority" (OTA).[31]

peer review

ABCELLERA

AbCellera

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From Wikipedia, the free encyclopedia

AbCellera Biologics Inc. is a Vancouver, British Columbia-based biotechnology firm that researches and develops human antibodies. The company is best known for its leading role in the Pandemic Prevention Platform, a project of DARPA's Biological Technologies Office.[1] AbCellera utilizes a proprietary technology platform, which they claim can develop "medical countermeasures within 60 days."[2] Its platform for single-cell screening was initially developed at the University of British Columbia.[3]

AbCellera Biologics Inc.

Company type	Public
Traded as	Nasdaq: ABCL
Industry	Biotechnology
Founded	2012; 12 years ago
Headquarters	Vancouver, British Columbia
Revenue	375.2 million (2021)
Number of employees	386 (2021)
Website	www.abcellera.com

History [edit]

AbCellera was founded in 2012 by biomedical researchers Carl Hansen, Véronique Lecault, Kevin Heyries, Daniel Da Costa and Oleh Petriv. In November 2016, the company received a US$645K grant from the Bill & Melinda Gates Foundation to develop a test for tuberculosis.[4] In September 2018, a $10M series A round of funding was closed.[5] In May 2020, a $105M series B round of funding was closed.[6][7]

In January 2017, AbCellera announced that it would be collaborating with Pfizer to discover and develop antibodies against "undisclosed membrane protein targets."[8][9]

ABCELLERA

COVID-19 and expansion [edit]

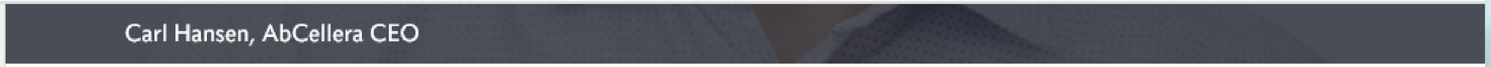
In June 2020, AbCellera announced it had begun the world's first study of a potential antibody treatment against COVID-19, with a Phase 1 trial of LY-CoV555 (Bamlanivimab), in collaboration with Eli Lilly and Company.[10] The drug was granted an Emergency Use Authorization by the U.S. Food and Drug Administration in November 2020, and subsequently renewed in February and March 2021.[11][12] The EUA was revoked in April 2021, with the FDA citing an updated conclusion that "the known and potential benefits of bamlanivimab alone no longer outweigh the known and potential risks for the product," because of significantly reduced efficacy against emerging variants of SARS-CoV-2.[13] In November 2020, Peter Thiel joined AbCellera's board of directors and disclosed a 5.3% stake in the company.[14][15]

In September 2021, the company announced a multi-year agreement with Moderna to develop mRNA-based antibody treatments against multiple diseases.[16]

In January 2022, the company received a $1.5 million grant from the Bill & Melinda Gates Foundation to identify monoclonal antibodies against respiratory syncytial virus (RSV).[17] A second COVID-19 monoclonal antibody therapy (Bebtelovimab) was given Emergency Use Authorization in February 2022, with the U.S. Government committing to a $720 million purchase of up to 600,000 doses.[18]

Other partnerships include collaborations with Ablynx, Gilead Sciences, GlaxoSmithKline, Merck, Novartis, Sanofi and Teva Pharmaceutical Industries.[19][20]

ENDPOINTS NEWS



February 14, 2022 07:06 AM EST | FDA+, Coronavirus

As Omicron rages, FDA clears Eli Lilly/ AbCellera's new antibody days after $720M supply deal



Amber Tong
Senior Editor

The FDA has authorized a new Covid-19 antibody from Eli Lilly and AbCellera, adding a much-needed weapon to the arsenal fighting against Omicron.

Just days ago, the two companies unveiled a $720 million deal to supply 600,000 doses of the drug, bebtelovimab, to the US government. It may now be prescribed, under emergency use authorization, to adults and teenagers 12 or older with positive SARS-CoV-2 tests who are either at high risk for progression to severe disease or unable/ineligible for alternative treatment options.

MOLNUPIRAVIR

Molnupiravir

Article Talk

From Wikipedia, the free encyclopedia

Molnupiravir, sold under the brand name **Lagevrio**, is an antiviral medication that inhibits the replication of certain RNA viruses.[7] It is used to treat COVID-19 in those infected by SARS-CoV-2.[7] It is taken by mouth.[7]

Molnupiravir is a prodrug of the synthetic nucleoside derivative N^4-hydroxycytidine and exerts its antiviral action by introducing copying errors during viral RNA replication.[13][14]

Molnupiravir was originally developed to treat influenza at Emory University by the university's drug innovation company, Drug Innovation Ventures at Emory (DRIVE), but was reportedly abandoned for mutagenicity concerns.[15][16] It was then acquired by Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[17]

MOLNUPIRAVIR

History [edit]

Molnupiravir was developed at Emory University by its drug innovation company, Drug Innovation Ventures at Emory (DRIVE).[17] In 2014, DRIVE began a screening project funded by the Defense Threat Reduction Agency to find an antiviral drug targeting Venezuelan equine encephalitis virus (VEEV), which led to the discovery of EIDD-1931.[33][*unreliable medical source?*] When turned into the prodrug EIDD-2801 (molnupiravir), the compound also showed activity against other RNA viruses including influenza, Ebola, chikungunya, and various coronaviruses.[33]

The international nonproprietary name of the drug was inspired by that of Thor's hammer, Mjölnir. The idea is that the drug will strike down the virus like a mighty blow from the god of thunder.[30]

In 2019, the National Institute of Allergy and Infectious Diseases (NIAID) approved moving molnupiravir into Phase I clinical trials for influenza.[33]

In March 2020, the research team pivoted to studying SARS-CoV-2, and successfully used molnupiravir to treat human cells infected with the novel coronavirus.[33][*unreliable medical source?*] A study found that it is orally active against SARS-CoV-2 in ferrets.[34]

DRIVE then licensed molnupiravir for human clinical studies to Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[33][17]

MOLNUPIRAVIR

Economics [edit]

In September 2021, Merck signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) that allows MPP to sublicense molnupiravir and supply the COVID-19 oral medication to 105 low- and middle-income countries. The cost of the US government's initial purchase was about $712 per course of treatment; treatment with generics in developing countries can cost as little as $20.[38][39]

Sales of molnupiravir were $952 million in the fourth quarter of 2021.[40]

Brand names [edit]

Molnupiravir is the international nonproprietary name.[53][54]

Generic versions are available under the brand names Molulife (Mankind),[55] Molena (Emcure),[56] and Esplevir (Promomed).[52]

Public health concerns [edit]

At a November 2021 AMDAC meeting, multiple advisors raised the concern that molnupiravir could accelerate the emergence of variants of concern.[57][58] Other scientists raised similar concerns both before and after the meeting.[59][25][60][24] These concerns were confirmed with the September 2023 publication of a study of 15 million global SARS-CoV-2 sequences: after molnupiravir had been introduced in 2022, genomic changes were more common, especially where it had been used.[26]

MOLNUPIRAVIR



clinical trial(s) summarized in the authorized labeling. Such materials must include any limitations of the clinical trial data as described in the authorized labeling. Merck may not imply that LAGEVRIO is FDA-approved for its authorized use by making statements such as "LAGEVRIO is safe and effective for the treatment of COVID-19."

AA. All descriptive printed matter, advertising, and promotional material, relating to the use of LAGEVRIO under this authorization clearly and conspicuously shall state that:

- LAGEVRIO has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults with mild-to-moderate COVID-19, who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate; and

- The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

If the Agency notifies Merck that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions Y through AA of this EUA, Merck must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.11.15 15:41:25 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b. Moderna[42]

Moderna is a biotechnology company based in the United States that has predominantly focused on development of mRNA therapeutic platforms. It undertook a successful initial public stock offering in 2018. Shortly following the pandemic outbreak, the US government entered into a development and purchase agreement with Moderna for what became its *Spikevax* vaccine, initially for USD 498 million, rising for procurement to approximately USD 10 billion by July 2022. The initial price per dose was approximately USD 16.80 per dose for the first 200 million doses.

The agreement with the US government required Moderna to produce its vaccines within the United States. Based on typical federal government procurement provisions, the US government would receive a nonexclusive license to practice the invention for its own purposes, and the US government secured "march-in" rights for patents secured based on US government funding. This gave the government the right to provide technology to third parties in the event Moderna did not supply vaccines on reasonable terms. (The US government has never exercised its "march-in" rights with respect to a pharmaceutical (including vaccine) product, despite being requested several times by public interest groups.)

Moderna in-licensed mRNA technology from the University of Pennsylvania, paying approximately USD 650 million in royalties (approximately 3.5 percent) by the end of 2021. In addition, Moderna recently agreed to pay USD 400 million ("delayed licensing" fee) to the US National Institutes of Health, Dartmouth College and Scripps Research for patented technology it used to stabilize mRNA-generated spike proteins.

Moderna entered into a large-scale contract manufacturing agreement with Lonza, a Swiss-based manufacturer, with production facilities in both the United States and Switzerland. Moderna licensed its IP to Lonza for purposes of manufacturing the mRNA vaccine, but each party otherwise retained rights in its own IP.

Moderna's "access policy" consisted of announcing that it would not assert its patents in infringement actions against third parties, updating that policy in March 2022 to limit the pledge to 92 Gavi-COVAX Advanced Market Commitment countries.

In December 2020 Moderna concluded an APA with the EU for an initial 80 million doses, with option for an additional 80 million doses, at a price of USD 22.50 per dose, including a nonrefundable down payment of USD 360 million. The EU subsequently expanded that commitment. The EU agreed that it would not obtain any rights in Moderna IP, and it would not export doses outside of Europe without Moderna's consent. Moderna engaged a Spanish manufacturer, ROVI, to perform fill and finish services in Europe, along with Lonza's Swiss manufacturing operation.

Moderna was criticized for delivering only a small percentage of its vaccine doses outside high income countries. It eventually offered doses to COVAX at a tiered price of USD 7–10 per dose.

Moderna is currently involved in litigation with a number of companies regarding entitlement to patented technologies. Among other things, Moderna has asserted that for certain actions arising out of its supply of COVID-19 vaccines it can only be sued as a US government contractor in the Federal Court of Claims, and not otherwise in private civil infringement litigation.[43]



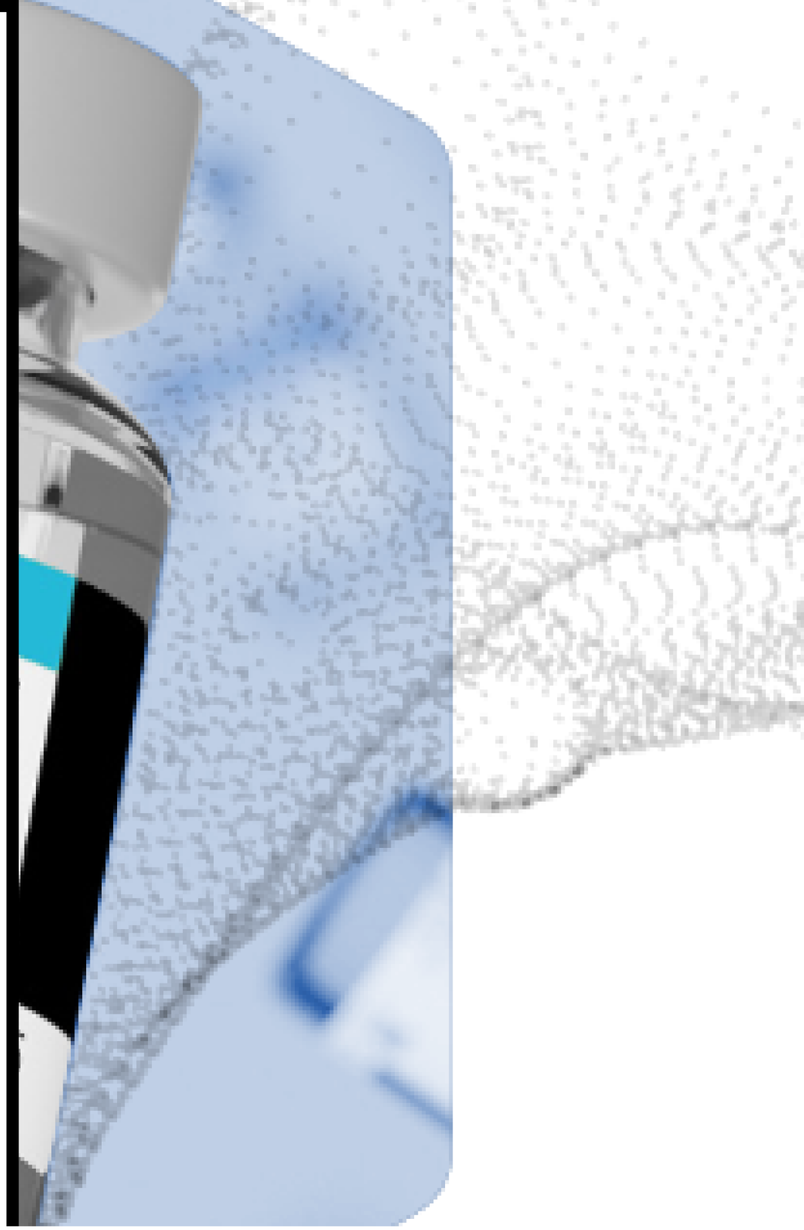
https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

Table 1 identifies several parameters of the 10 vaccine developers and suppliers covered by the study, including the nature of the enterprise, the source of their funding, the underlying vaccine technology, their articulated access policies and the reported price of the vaccines they supplied during the COVID-19 pandemic.

Table 1 Parameters of the 10 vaccine developers and suppliers covered by the study

	Pfizer/ BioNTech	Moderna	AstraZeneca-Oxford – SII	Johnson & Johnson/ Janssen	Novavax	CureVac	Baylor/ Texas Children's Hospital	PRC – Sinovac; Sinopharm	Gamaleya/ Russian Federation
Type of entity	Private (securities market)	Private (securities market)	Private (securities market/ university)	Private (securities market)	Private (securities market)	Private (securities market)	University (private); hospital (private)	Private/ state owned	State owned
Source of funding	Private market plus APA	US gov't funded development and APA	Foundations (CEPI-Gates); US development and APA; UK development and APA; EU APA	US gov't development and APA	US gov't development and APA; CEPI development and APA	CEPI; German gov't ; EU APA	Self-funded; CEPI (for Dynavax)	Self-funded and government supported	State funded
Vaccine technology	mRNA-based	mRNA-based	Modified adenovirus	Modified adenovirus	Recombinant DNA	mRNA-based (abandoned)	Recombined protein fragment	Inactivated virus	Dual adenovirus vector
Access provisions	Tiered pricing	No patent enforcement pledge	General intent on favorable access for developing countries	Supply at not-for-profit price	Affordable prices	Per CEPI equitable access guidelines	Unknown	Unknown	Unknown
Pricing	US gov't: USD 20–30/dose; EU: EUR 19.5; Peru, Albania, Colombia, Dom. Rep.: USD 12	US gov't: USD 15.25–25.36/dose; EU: USD 22.50, COVAX USD 7–10; Botswana: USD 28.88; Argentina: USD 21.50	EU: EUR 2.9/ dose; UK: (at cost); Brazil: USD 3.16–5.27; Colombia: USD 6, SII-CEPI USD 2.50	US: USD 10/ dose; EU: USD 8.50, COVAX USD 5–8	EU – Denmark: USD 20.90	EU: EUR 10/ dose	India: USD 1.75 (public), USD 3–10 (private)	PRC, both Sinovac and Sinopharm: USD 29.75; Zimbabwe: USD 7, Sinopharm; Hungary: USD 36, Sinovac; Indonesia: USD 17	From USD 9.75 (Guatemala) to USD 27.15 (Pakistan, private)

The findings of the case studies are summarized in this section, with substantially greater detail provided in Annex 1.



https://www.wipo.int/edocs/pubdocs/en/wipo-pub
rn2023-39-en-intellectual-property-and-technology
transfer-for-covid-19-vaccines-assessment-of-the
record.pd

a. Pfizer/BioNTech[38]

At the earliest stage of the pandemic outbreak, Pfizer, based in the United States, successfully negotiated to acquire rights to mRNA vaccine technology from BioNTech, based in Germany. Pfizer paid BioNTech nearly USD 1 billion for those rights, and agreed to a 50-50 split of gross profits from sales of a resulting vaccine. BioNTech's technology was protected by patents. Pfizer would distribute its vaccine (*Comirnaty*) to most of the world, with BioNTech retaining rights for Germany and Türkiye, and with BioNTech preserving a licensing agreement with a PRC biotechnology company, Fosun, on behalf of the partners (for which Fosun agreed to pay up to USD 85 million in fees and a 35 percent share of gross profits). For reasons which remain unclear, the Pfizer BioNTech vaccine was not introduced in the PRC until quite recently and in limited quantity.

Pfizer and BioNTech entered into a complex Collaboration Agreement that largely gave decision-making control to Pfizer, including with respect to pricing of the vaccines outside Germany and Türkiye. Each party would retain ownership of its solely developed IP, and the parties would jointly own collaboratively developed IP. BioNTech had previously in-licensed mRNA technology from the University of Pennsylvania/Cellscript and Acuitas, each of which received significant royalties based on sales of the vaccine.

Pfizer came into the collaboration with a sophisticated manufacturing and distribution operation within the United States, and most of its manufacturing at least at the initial stages was undertaken in the United States. Unique among the major vaccine developers, Pfizer did not benefit from a technology development agreement with the US government, but it did receive an order for 300 million doses of its vaccine for a total price of USD 5.97 billion in March 2021 (a per dose price of USD 19.90). As of December 2022, the US government had paid more than USD 15 billion to Pfizer/BioNTech for about 655 million doses. As a consequence of going without a development subsidy, the US government did not secure typical Bayh-Dole "march-in" rights with respect to patents from Pfizer.

The European Union (EU) also entered into a large-scale APA in November 2020 with Pfizer/BioNTech, for up to 300 million doses at a price of EUR 19.5 per dose. Pfizer/BioNTech entered into a number of additional agreements to supply other countries, including Peru, Colombia, the Dominican Republic and Albania. The price per dose in each of these contracts was USD 12, without firm commitment on delivery schedule. Pfizer/BioNTech would retain ownership of all IP. Note that Pfizer's agreements with the US government did not require it to supply LMICs at preferential prices.

Pfizer's chief executive officer (CEO) objected to the proposal for a WTO TRIPS waiver, arguing that Pfizer was limited in its supply capacity by shortages of component materials, and that opening up the supply market to more potential producers would exacerbate the problem. He also suggested that LMICs were reluctant to purchase the mRNA vaccine because of cold chain storage limitations.[39]

There is no evidence suggesting that Pfizer/BioNTech affirmatively threatened any party with patent infringement litigation intended to block production during the course of the pandemic. It is currently involved in litigation with Moderna, among others, regarding rights to patented technologies.[40] The litigation with Moderna – which Moderna initiated in the United States and Germany – has been extending to additional jurisdictions, including Belgium, Ireland and the United Kingdom. Pfizer and BioNTech have counterclaimed.[41]



https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

Safety, tolerability, pharmacokinetics, and immunogenicity of the therapeutic monoclonal antibody mAb114 targeting Ebola virus glycoprotein (VRC 608): an open-label phase 1 study

*Martin R Gaudinski, Emily E Coates, Laura Novik, Alicia Widge, Katherine V Houser, Eugeania Burch, LaSonji A Holman, Ingelise J Gordon, Grace L Chen, Cristina Carter, Martha Nason, Sandra Sitar, Galina Yamshchikov, Nina Berkowitz, Charla Andrews, Sandra Vazquez, Carolyn Laurencot, John Misasi, Frank Arnold, Kevin Carlton, Heather Lawlor, Jason Gall, Robert T Bailer, Adrian McDermott, Edmund Capparelli, Richard A Koup, John R Mascola, Barney S Graham, Nancy J Sullivan, Julie E Ledgerwood, on behalf of the VRC 608 Study team**

Summary

Background mAb114 is a single monoclonal antibody that targets the receptor-binding domain of Ebola virus glycoprotein, which prevents mortality in rhesus macaques treated after lethal challenge with *Zaire ebolavirus*. Here we present expedited data from VRC 608, a phase 1 study to evaluate mAb114 safety, tolerability, pharmacokinetics, and immunogenicity.

Methods In this phase 1, dose-escalation study (VRC 608), conducted at the US National Institutes of Health (NIH) Clinical Center (Bethesda, MD, USA), healthy adults aged 18–60 years were sequentially enrolled into three mAb114 dose groups of 5 mg/kg, 25 mg/kg, and 50 mg/kg. The drug was given to participants intravenously over 30 min, and participants were followed for 24 weeks. Participants were only enrolled into increased dosing groups after interim safety assessments. Our primary endpoints were safety and tolerability, with pharmacokinetic and anti-drug antibody assessments as secondary endpoints. We assessed safety and tolerability in all participants who received study drug by monitoring clinical laboratory data and self-report and direct clinician assessment of prespecified infusion-site symptoms 3 days after infusion and systemic symptoms 7 days after infusion. Unsolicited adverse events were recorded for 28 days. Pharmacokinetic and anti-drug antibody assessments were completed in participants with at least 56 days of data. This trial is registered with ClinicalTrials.gov, number NCT03478891, and is active but no longer recruiting.

Findings Between May 16, and Sept 27, 2018, 19 eligible individuals were enrolled. One (5%) participant was not infused because intravenous access was not adequate. Of 18 (95%) remaining participants, three (17%) were assigned to the 5 mg/kg group, five (28%) to the 25 mg/kg group, and ten (55%) to the 50 mg/kg group, each of whom received a single infusion of mAb114 at their assigned dose. All infusions were well tolerated and completed over 30–37 min with no infusion reactions or rate adjustments. All participants who received the study drug completed the safety assessment of local and systemic reactogenicity. No participants reported infusion-site symptoms. Systemic symptoms were all mild and present only in four (22%) of 18 participants across all dosing groups. No unsolicited adverse events occurred related to mAb114 and one serious adverse event occurred that was unrelated to mAb114. mAb114 has linear pharmacokinetics and a half-life of 24·2 days (standard error of measurement 0·2) with no evidence of anti-drug antibody development.

Interpretation mAb114 was well tolerated, showed linear pharmacokinetics, and was easily and rapidly infused, making it an attractive and deployable option for treatment in outbreak settings.

Funding Vaccine Research Center, US National Institute of Allergy and Infectious Diseases, and NIH.

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Introduction

Ebolaviruses are negative-strand RNA viruses with five species,[1,2] three of which are known to induce haemorrhagic fever in humans: *Bundibugyo ebolavirus*, *Sudan ebolavirus*, and *Zaire ebolavirus* (EBOV).[3] Outbreaks probably begin by zoonotic transmission to humans after exposure to fruit bats or other infected animals which spread through the community by direct contact with blood, bodily fluids, or organs of infected people or corpses.[4–7] Ebola virus disease becomes symptomatic after a 2–21 day incubation period and causes severe systemic illness characterised by fever, fatigue, myalgia, headache, pharyngitis, vomiting, diarrhoea, rash, kidney and liver dysfunction, and bleeding diathesis, with case fatality rates ranging from 25–90%.[3,8] The 2014 west Africa EBOV outbreak, in which the first case was reported in December, 2013, and the last case in June, 2016, was the largest outbreak to date, with

Lancet 2019; 393: 889–98

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This online publication has been corrected. The corrected version first appeared at thelancet.com on May 28, 2020

See Comment page 850

*Listed at the end of the Article

Vaccine Research Center (M R Gaudinski MD, L E Coates PhD, L Novik MA, A Widge MD, K V Houser PhD, E Burch MPH, L A Holman FNP, I J Gordon RN, G L Chen MD, C Carter MD, S Sitar MS, G Yamshchikov MS, N Berkowitz MPH, C Andrews MS, S Vazquez MS, C Laurencot PhD, J Misasi MD, F Arnold PhD, K Carlton MBA, H Lawlor MS, J Gall PhD, R T Bailer PhD, Prof A McDermott PhD, Prof R A Koup MD, Prof J R Mascola MD, Prof B S Graham MD, Prof N J Sullivan PhD, Prof J E Ledgerwood DO) and Biostatistics Research Branch, Division of Clinical Research (M Nason PhD), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA; and School of Medicine and Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California San Diego, San Diego, CA, USA (Prof E Capparelli PharmD)

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PMID: 34526994

Journal Article

Review: Insights on Current FDA-Approved Monoclonal Antibodies Against Ebola Virus Infection

Olivier Tshiani Mbaya,[1,*] Philippe Mukumbayi,[2] and Sabue Mulangu[3]

▾ Author information ▸ Article notes ▸ Copyright and License information PMC Disclaimer

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8435780/

Ebola outbreak treatment trial narrowed to two promising drugs

Lisa Schnirring | News Editor | CIDRAP News, August 12, 2019

Topics: Ebola , Viral Hemorrhagic Fever

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Global health officials today announced a pause in the clinical trial of four investigational Ebola drugs in the Democratic Republic of Congo (DRC) outbreak region after an early look at the data found that two of the drugs—Regeneron and mAb 114—stood out as more effective.

In other outbreak developments, the DRC reported 38 more cases since Aug 9, lifting the outbreak total past 2,800 to 2,831.



Get CIDRAP updates

Latest outbreak numbers

In updates to the WHO's Ebola dashboard, the DRC reported 8 more cases on Aug 10, 15 more on Aug 11, and 15 more cases today, putting the overall total at 2,831.

Health officials are still investigating 326 suspected infections.

Since Aug 9, 21 more people died from the disease, lifting the fatality count to 1,888.

https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs

Journal of Exposure Science & Environmental Epidemiology www.nature.com/jes

ARTICLE OPEN

Check for updates

The size and culturability of patient-generated SARS-CoV-2 aerosol

Joshua L. Santarpia[1,2,3,11]✉, Vicki L. Herrera[1,2], Danielle N. Rivera[3], Shanna Ratnesar-Shumate[1,2], St. Patrick Reid[1,2,11], Daniel N. Ackerman[3], Paul W. Denton[4], Jacob W. S. Martens[4], Ying Fang[5], Nicholas Conoan[6], Michael V. Callahan[7], James V. Lawler[2,8], David M. Brett-Major[2,9] and John J. Lowe[2,10,11]

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BACKGROUND: Aerosol transmission of COVID-19 is the subject of ongoing policy debate. Characterizing aerosol produced by people with COVID-19 is critical to understanding the role of aerosols in transmission.
OBJECTIVE: We investigated the presence of virus in size-fractioned aerosols from six COVID-19 patients admitted into mixed acuity wards in April of 2020.
METHODS: Size-fractionated aerosol samples and aerosol size distributions were collected from COVID-19 positive patients. Aerosol samples were analyzed for viral RNA, positive samples were cultured in Vero E6 cells. Serial RT-PCR of cells indicated samples where viral replication was likely occurring. Viral presence was also investigated by western blot and transmission electron microscopy (TEM).
RESULTS: SARS-CoV-2 RNA was detected by rRT-PCR in all samples. Three samples confidently indicated the presence of viral replication, all of which were from collected sub-micron aerosol. Western blot indicated the presence of viral proteins in all but one of these samples, and intact virions were observed by TEM in one sample.
SIGNIFICANCE: Observations of viral replication in the culture of submicron aerosol samples provides additional evidence that airborne transmission of COVID-19 is possible. These results support the use of efficient respiratory protection in both healthcare and by the public to limit transmission.

Keywords: SARS-CoV-2; aerosol transmission; viral aerosol; human-generated aerosol

Journal of Exposure Science & Environmental Epidemiology; https://doi.org/10.1038/s41370-021-00376-8

MICHAEL V. CALLAHAN

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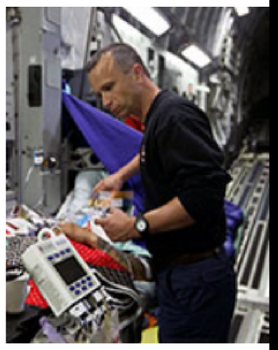
The War on Bugs

Michael Callahan: Alumni Profile

By Matt Windsor

Michael V. Callahan, M.D., DTM&H (U.K.), M.S.P.H., doesn't wear a military uniform, but he plays a crucial role in keeping Americans safe by beefing up the nation's defenses against disease.

For the past seven years, Callahan, a 1995 School of Medicine graduate, has been a program manager for the Defense Advanced Research Projects Agency (DARPA), the American military's secretive R&D center. Callahan was recruited while working overseas "to work on fast-paced solutions to health threats," he says. His biggest mission: Create a government-funded drug research and production capability focused strictly on national priorities, such as defense and pandemic preparedness, rather than profits. The Department of Defense had no idea how to make drugs, but they knew they had to learn, Callahan recalls.



Michael Callahan directing an air evacuation of a U.S. serviceperson with infectious disease from Africa

Rush Request

ALEX AZAR

Alex Azar

Article Talk

From Wikipedia, the free encyclopedia

Alex Michael Azar II (/ˈeɪzɑːr/; born June 17, 1967) is an American attorney, businessman, lobbyist, and former pharmaceutical executive who served as the U.S. Secretary of Health and Human Services from 2018 to 2021. Azar was nominated to his post by President Donald Trump on November 13, 2017, and confirmed by the United States Senate on January 24, 2018. He was also chairman of the White House Coronavirus Task Force from its inception in January 2020 to February 2020, when he was replaced by Vice President Mike Pence.

Personal details	
Born	Alex Michael Azar II June 17, 1967 (age 56) Johnstown, Pennsylvania, U.S.
Political party	Republican
Spouse	Jennifer Reist[1]
Children	2
Education	Dartmouth College (BA) Yale University (JD)
Occupation	Politician · attorney · businessman · lobbyist · former pharmaceutical executive

Alex Azar



Official portrait, 2019

ALEX AZAR



Official portrait, 2019

Eli Lilly and Company [edit]

In June 2007, Azar was hired by Eli Lilly and Company chief executive officer Sidney Taurel to be the company's top lobbyist and spokesman as its senior vice president of corporate affairs and communications.[7][20] Azar left the position after the 2008 United States presidential election was won by Democratic Party

In April 2009, Azar became vice president of Lilly's U.S. Managed Healthcare Services organization and its Puerto Rico affiliate.[21] In 2009, the company paid $1.415 billion to settle criminal charges regarding its promotion of antipsychotic drug Zyprexa (olanzapine) for off-label uses between 1999 and 2005.[20]

Effective January 1, 2012, Azar became president of Lilly USA, LLC, the largest division of Eli Lilly and Company, and was responsible for the company's entire operations in the United States.[21] Prices for drugs rose substantially under Azar's leadership, including the tripling of the cost of the company's top-selling insulin drug. Also under Azar's watch, Eli Lilly was one of three companies accused in a class-action lawsuit of exploiting the drug pricing system to increase profits for insulin. Eli Lilly was also fined in Mexico for colluding on the price of insulin.[22][23]

In connection with the position, Azar served on the board of directors of the Biotechnology Innovation Organization, a pharmaceutical lobby.[24]

In January 2017, Azar resigned from Eli Lilly "to pursue other career opportunities" as a result of a company reorganization.[25] He also resigned from the board of directors of the Biotechnology Innovation Organization. In his last year at the corporation he earned $2 million.[26]

DARPA

More

The Defense Advanced Research Projects Agency (DARPA) is a research and development agency of the United States Department of Defense.

Formed	February 7, 1958 (as ARPA)
Headquarters	Arlington County, Virginia, U.S.
Employees	220

DARPA was initiated on February 7, 1958 by President Dwight D. Eisenhower in response to the Soviet launching of Sputnik 1 in 1957 [2] [3]. Originally known as the Advanced Research Projects Agency (ARPA), the agency was created to facilitate research in technology with potential military applications [3].

1	Spanish flu	Influenza A/H1N1	17–100 million	1–5.4% of global population[5]	1918–1920	Worldwide
10	1918–1922 Russia typhus epidemic	Typhus	2–3 million	1–1.6% of Russian population[15]	1918–1922	Russia
11	1957–1958 influenza pandemic	Influenza A/H2N2	1–4 million	–	1957–1958	Worldwide
12	Hong Kong flu	Influenza A/H3N2	1–4 million	–	1968–1969	Worldwide
3	**HIV/AIDS pandemic**	**HIV/AIDS**	**43 million (as of 2024)**	[a]	**1981–present**[7]	**Worldwide**
5	**COVID-19 pandemic**	**COVID-19**	**7–35 million**[9][10] **(as of 2024)**	[a]	**2019**[b]**–present**[11][12][c]	**Worldwide**

Frank Kendall III

7 languages

Article Talk | Read Edit View history Tools

From Wikipedia, the free encyclopedia

Frank Kendall III (born January 26, 1949) is an American engineer, lawyer and executive who is the 26th and current United States Secretary of the Air Force. He has served in several senior positions in the U.S. Department of Defense.[1] A West Point graduate (Class of 1971, Distinguished Graduate),[2] he retired as a lieutenant colonel from the U.S. Army Reserve. From 2011 to 2017, Kendall served as the Under Secretary of Defense for Acquisition, Technology and Logistics in the Obama Administration.[3][4][5][2] He is a member of the Democratic Party.

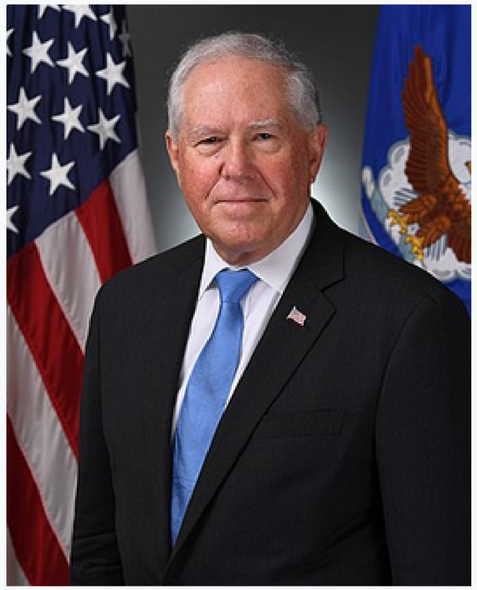
Early career [edit]



Kendall during his tenure as acting Deputy Director, 1989

Kendall began his career as a U.S. Army officer. After several assignments including postings to Germany and teaching engineering at West Point, he joined the civil service working as a systems engineer in missile defense. In 1986, he became the Assistant Deputy Under Secretary for Strategic Defense Systems as a member of the Senior Executive Service. From 1989 to 1994, he served as acting and then permanent Deputy Director of Defense Research and Engineering with responsibility for all U.S. conventional weapon systems research and development programs. After leaving government service in 1994, Kendall served as Corporate Vice President of Engineering at Raytheon and later as a consultant. During this period, Kendall acquired a J.D. degree from Georgetown University Law Center and worked on a pro bono basis as a human rights attorney.[6]

Frank Kendall



26th United States Secretary of the Air Force

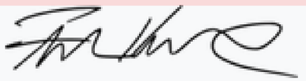
Incumbent

Assumed office
July 28, 2021

President	Joe Biden
Deputy	Gina Ortiz Jones Kristyn E. Jones (acting)
Preceded by	Barbara Barrett

Frank Kendall III

During his tenure as Under Secretary, Kendall implemented policies that led to substantial improvements in the cost and schedule performance of the Defense Department's weapons acquisition programs.[8] In 2016, he was recognized as Person of the Year by Aviation Week and Space Technology for his cost control efforts.[9] In addition to the policy changes he initiated and executed under the "Better Buying Power" initiatives he directly oversaw over 50 of the largest defense weapons programs. Examples include the F-35 Joint Strike Fighter program where he froze production for two years to incentivize efforts to stabilize the design,[10] the GPS 3 ground system, OCX, where he led the effort to restructure and complete this troubled program.[11] He oversaw the initiation of the development of the B-21 Long Range Strike Bomber which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]

Preceded by	Ash Carter
Succeeded by	Ellen Lord
Personal details	
Born	January 26, 1949 (age 75) Pittsfield, Massachusetts, U.S.
Political party	Democratic
Education	United States Military Academy (BS) California Institute of Technology (MS) Long Island University (MBA) Georgetown University (JD)
Signature	
Military service	
Branch/service	U.S. Army Reserve
Rank	Lieutenant colonel

Frank Kendall III

which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]

Biden Administration [edit]

On April 27, 2021, President Joe Biden announced Kendall as his nominee to be the 26th Secretary of the Air Force.[23] His Senate confirmation occurred after almost three months of deliberation, due to holds by Senators Mike Lee,[24] Gary Peters[25] and Elizabeth Warren,[26] the latter of whom released her hold after Kendall agreed to extend his post-governmental recusal agreements from two to four years.[26] Kendall was eventually confirmed by voice vote on June 26, 2021,[27][28] administratively sworn in on July 28, 2021[29] and ceremonially sworn in by Secretary of Defense Lloyd Austin on August 4, 2021.[30]

OWS SPENT 1.5 BILLION ON MODERNA TO PROVIDE A C19 "VACCINE"

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Lonza Group AG was founded in 1897 in Gampel, Switzerland.

MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN



NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.

FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN. ADDITIONALLY BORIO IS VP OF IN-Q-TEL.

ALSO ON THE BOARD FOR RESILIENCE IS FORMER FDA COMMISSIONER SCOTT GOTTLIEB AND CHRIS DARBY PRESIDENT OF IN-Q-TEL





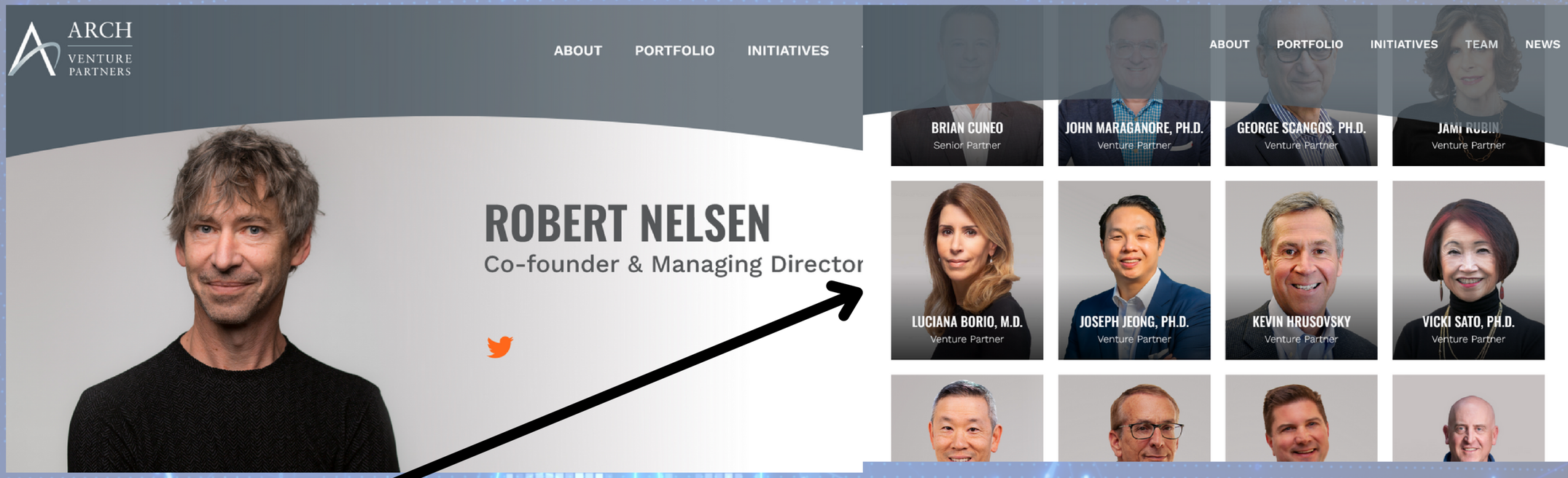


ALSO ON THE BOARD IS JOE LONSDALE, FOUNDER OF PALANTIR



PALANTIR WAS FUNDED BY IN-Q-TEL

PALANTIR CREATED THE TIBERIUS PROGRAM WHICH WAS THE SOFTWARE THAT RAN OWS



BORIO ON THE BOARD FOR NELSEN'S COMPANY ARCH

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To learn more about the JPEO-CBRND, visit: https://www.jpeocbrnd.osd.mil/, or follow the JPEO-CBRND on social media @JPEOCBRND.

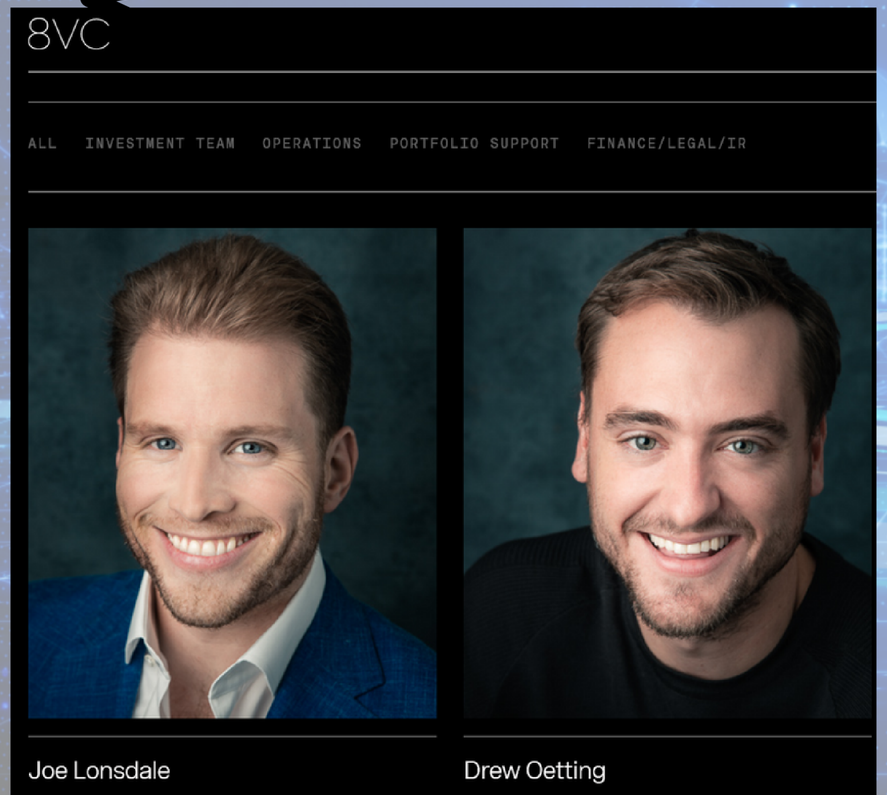
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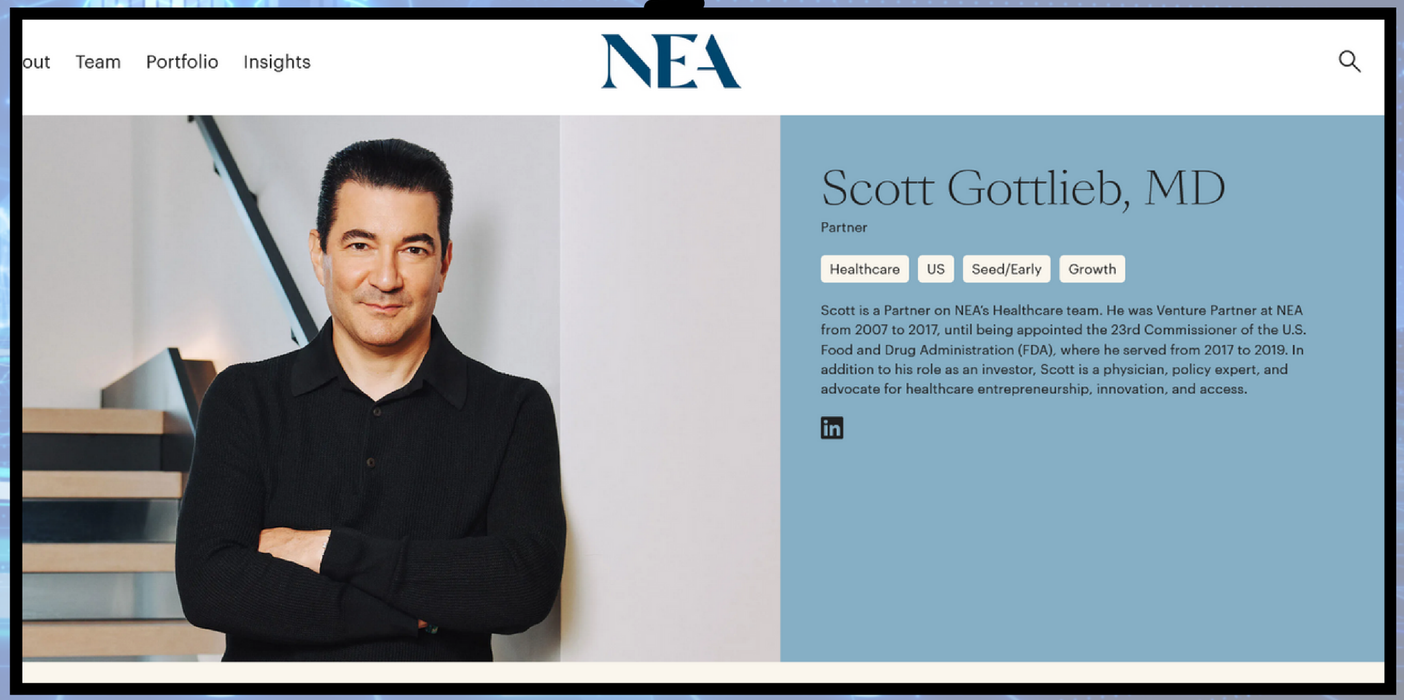
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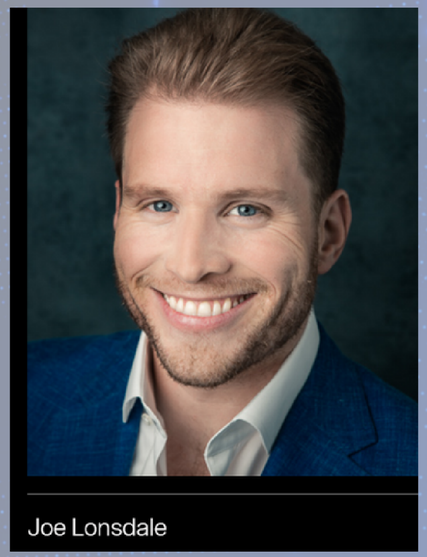
8VC

G/

NEA®







Joe Lonsdale founded Palantir.

Palantir created the software for Operation Warp Speed

Palantir



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ACQUISITION

HHS renews, expands Palantir's Tiberius contract to $31M

The scope of the COVID-19 vaccine distribution platform has grown and with it the price tag.

BY DAVE NYCZEPIR • JULY 26, 2021

The Department of Health and Human Services renewed and expanded its one-year contract for its COVID-19 vaccine distribution platform Tiberius from nearly $17 million to $31 million, tech company Palantir announced Monday.

Palantir Foundry powers Tiberius, which has grown from simply helping HHS understand vaccine distribution across the U.S. and providing an integrated view of the supply chain to serving as the backbone of day-to-day dosage programs launched by agencies like the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority.

HHS had Palantir develop Tiberius in mid-2020 as part of the Trump administration's Operation Warp Speed, which has since been rebranded as the Countermeasure Acceleration Group.

Board of Directors

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Robert Nelsen

Chairman and Founder, ARCH



Patrick Y. Yang, PhD

Vice Chairman, Former EVP Juno, Roche, Genentech



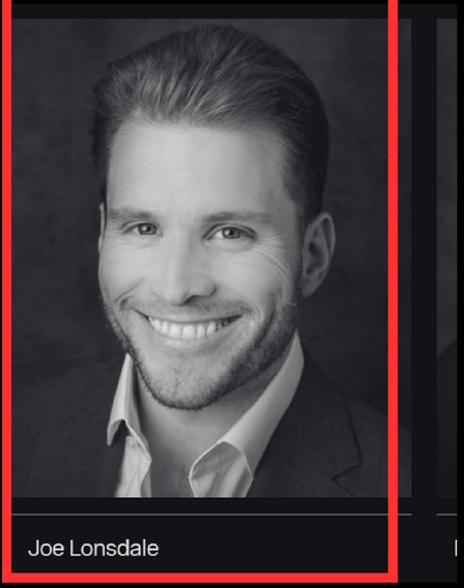
Drew Oetting

Co-founder & President, 8VC, Co-founder Affinity



Rahul Singhvi, ScD

Co-founder, CEO





Frances Arnold, PhD

Nobel Prize Laureate, CalTech Professor



George Barrett

Former Chairman & CEO, Cardinal Health



Mitchell E. Daniels, Jr.

President, Purdue University, Former Governor of Indiana



Chris Darby

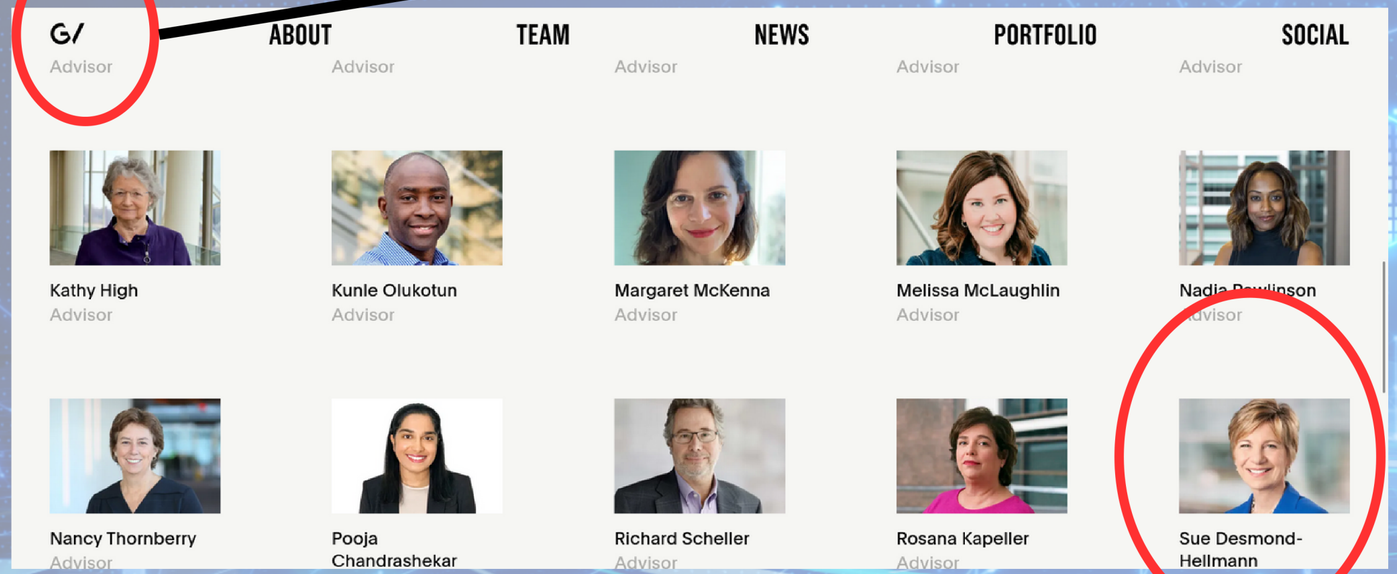
CEO, In-Q-Tel

ALL HIGHLIGHTED INDIVIUALS HAVE TIES TO THE INTELLIGENCE COMMUNITY

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GV = GOOGLE VENTURES
FORMER BILL & MELINDA GATES FOUNDATION CEO AND CURRENT BOARD MEMBER OF: RESILIENCE AND PFIZER,



Launched as Google Ventures in 2009, GV originated as an independent venture capital firm for innovative founders. While today we're formally known as GV, our previous moniker (Google Ventures) is the root of our DNA. With Alphabet as our sole limited partner, we focus all our energy on meeting and supporting founders at the earliest stages of company-building. GV's operating partners work to support startups across design, equity, diversity & inclusion, talent, and engineering. GV also helps startups interface with Google, providing unique access to the world's best technology and talent.

GV operates on long time horizons and deals in decades — not rounds. At launch, we had a $60 million capital commitment and a desire to partner with founders moving the world forward. Today, GV has over $10 billion in assets under management, 400 active portfolio companies across North America and Europe, and notable investment outcomes including Uber, Nest, Slack, GitLab, Duo Security, Flatiron Health, Verve Therapeutics, and One Medical.

SUSAN DESMOND - HELLMAN

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Freda Lewis-Hall, MD,



Scott Gottlieb, MD



Frances Arnold, PhD

Pfizer

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Dr. Freda Lewis-Hall Joins Pfizer As Chief Medical Officer

Monday, May 04, 2009 - 06:46am

Prominent Physician, Researcher and Business Leader Will Direct Global Medical and Regulatory Strategy, Join Executive Leadership Team

(BUSINESS WIRE)--Pfizer Inc announced today that Freda Lewis-Hall, M.D., has been appointed as Chief Medical Officer and Senior Vice President, Pfizer Inc. Dr. Lewis-Hall will be the senior physician in the company, responsible for enterprise-wide medical, patient safety, regulatory affairs and quality assurance as well as outreach to doctors and other medical professionals. She joins Pfizer from Vertex Pharmaceuticals, where she was responsible for clinical and non-clinical development as well as both medical and regulatory.

Pfizer

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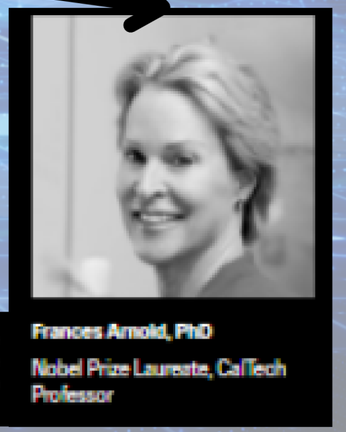


Scott Gottlieb, M.D.

Age: 51 years

Partner, New Enterprise Associates, Inc.'s Healthcare Investment Team and Resident Fellow of the American Enterprise Institute since 2019. Served as the 23rd Commissioner of the FDA from 2017 to 2019. Prior to serving as Commissioner of the FDA, Dr. Gottlieb held several roles in the public and private sectors, including serving as a Venture Partner to New Enterprise Associates, Inc. from 2007 to 2017.

Director of Illumina, Inc. Director of Aetion, Inc. a private healthcare data technology company, and Tempus, a private technology company. Board Member of National Resilience, Inc. Scientific Advisory Board Member of CellCarta. Member of the National Academy of Medicine and a contributor to the financial news network CNBC.



ROBERT NELSEN & LUCIANA BORIO



Bob Nelsen

Nelsen and Borio have worked closely in the past. He previously told *Endpoints News* that he spent last spring in his Seattle home, talking on the phone with Borio about her work running pandemic preparedness on the NSC, and fuming with her about the dire state of American manufacturing. Those talks helped lead to the launch of Nelsen's $800 million biologics manufacturing startup Resilience.

Borio, who previously served as the FDA's acting chief scientist and as VP at that nonprofit investment firm In-Q-Tel, serves as a senior fellow for global health at the Council on Foreign Relations for about the last year. Borio did not respond to a request for comment on whether she would keep that role at the CFR. She also serves as a member of CEPI's scientific advisory committee, where she provides Covid-related guidance and work on the public-private partnership's $3.5 billion plan to reduce the threat of future pandemics and epidemics.

And she played a hand in President Biden's race to nominate an FDA commissioner, according to one former agency official

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BOTH ON THE COUNCIL FOR FOREIGN RELATIONS

BOTH MEMBERS OF ARCH VENTURES

BOTH PLAYED KEY ROLES IN THE "CREATION OF RESILIENCE"

During the saga around the first accelerated approval for Sarepta Therapeutics' DMD drug eteplirsen, Borio — then FDA's acting chief scientist — wrote to then-FDA commissioner Robert Califf with fears that current acting commissioner Jane Woodcock "chilled scientific debate within (the FDA Center for Drug Evaluation and Review) and reduced the level of participation by the review team during the f nal stages of the decision-making process."

A former senior FDA official said it was this dispute that led Woodcock to push Bo rio out of the FDA entirely, after Borio circulated an internal memo concerning Woodcock's role with Sarepta. This former official also said he thinks Borio, who was vetted but ultimately not nominated to lead FDA, might have a hand in icing Woodcock's failure to land a nomination, too.

"SINGHVI WAS ...AND AN OPERATING PARTNER AT FLAGSHIP PIONEERING, WHICH PLAYED A MAJOR ROLE IN THE CREATION OF MODERNA"

Prior to Resilience, Singhvi was CEO of Novavax and an operating partner at Flagship Pioneering, which played a major role in the creation and rise of Moderna.

Resilience was co-founded by Biotech venture capitalist Robert Nelsen, who is known for listening "to science's earliest whispers, even when data are too early for just about anyone else."

Nelsen was one of the earliest investors in Illumina, a California-based gene-sequencing hardware and software giant that is believed to currently dominate the field of genomics.

As mentioned in a previous Unlimited Hangout investigation, Illumina is closely tied to the Defense Advanced Research Projects Agency (DARPA) equivalent of the Wellcome Trust known as Wellcome Leap, which is also focused on "futuristic" and transhumanist "medicines."

Nelsen is now chairman of National Resilience's board, which is a "Who's Who" of big players from the U.S. National Security State, Big Pharma and Pharma-related "philanthropy."

HTTPS://CHILDRENSHEALTHDEFENSE.ORG/DEFENDER/CIA-LINKED-MRNA-MODERNA-OMICRON-COVID-BOOSTER-SHOT/

CHILDREN'S HEALTH DEFENSE ET. WHITNEY WEBB

LUCIANA BORIO

Expert Bio

Luciana Borio is a senior fellow for global health at the Council on Foreign Relations (CFR). She also is a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies.

GOTTLIEB



Scott Gottlieb, MD
@ScottGottliebMD · **Follow**

Big congratulations to @llborio and to @rtnarch and the team at Arch Ventures. Dr. Borio is a great colleague and brings a deep record of skill and accomplishment at FDA and NSC to this new role; where she'll continue to advance innovation, science, and public health.

> **BioCentury** @BioCentury
> Luciana Borio (@llborio) joins Arch as venture partner, brings expertise, FDA, White House experience in biodefense and public health and will focus on manufacturing, clinical trials, novel therapies. Firm promotes Carol Suh to partner buff.ly/3zIRFWX

11:46 PM · Jul 23, 2021

62 **See the latest COVID-19 information on Twitter**

On November 9, 2020, U.S. president-elect Joe Biden named Borio to be one of the 13 members of his COVID-19 Advisory Board.[9]

activities for the Office of Preparedness and Response.[12] Before leaving her role as assistant commissioner of FDA, she approved a partnership in infectious disease research with the Bill & Melinda Gates Foundation.[13]

In 2020, Borio was appointed by the Council on Foreign Relations to serve on its Independent Task Force on Improving Pandemic Preparedness, co-chaired by Sylvia Mathews Burwell and Frances Townsend.[14]

Other activities [edit]

- Codagenix, Member of the Scientific Advisory Board[15]
- Goldman Sachs, Consultant[16]



WSJ | OPINION

JAN 28 2020

English Edition | January 29, 2020 | Print Edition

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OPINION | COMMENTARY

Act Now to Prevent an American Epidemic

Quarantines, flu vaccines and other steps to take before the Wuhan virus becomes widespread.

By Luciana Borio and Scott Gottlieb

Jan. 28, 2020 6:48 pm ET

PRINT TEXT 105

GOTTLIEB & LUCIANA BORIO

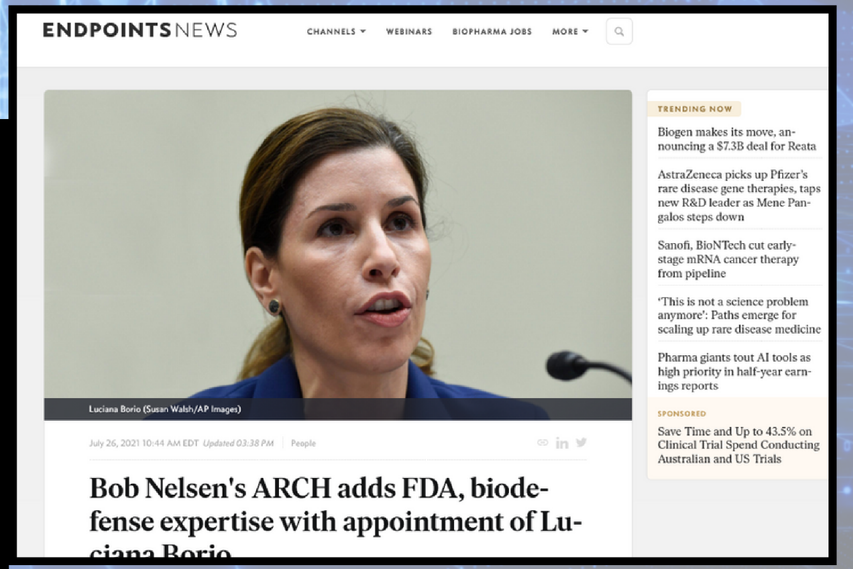


Gottlieb: There will be a rapid acceleration of coronavirus cases in US

192K views • 4 years ago

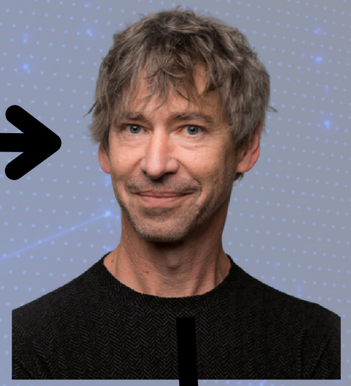
CNBC Television

Dr. **Luciana Borio**, vice president of In-Q-Tel and former Director of Medical and Biodefense Preparedness policy for the White ...



moderna

RESILIENCE®



MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN

WHO MADE ROBERT NELSEN THE HEAD OF THE BOARD OF DIRECTORS



NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.

- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. [1] [2] [3] [4] [5]

BORIO IS ALSO A JOHNS HOPKINS GRAD, FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN







Palantir



HEADS OF OWS:

MONCEF SLAOUI

MATTHEW HEPBURN [DARPA]

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach

Authors: Moncef Slaoui, Ph.D., and Matthew Hepburn, M.D. Author Info & Affiliations

Published August 26, 2020 | N Engl J Med 2020;383:1701-1703
DOI: 10.1056/NEJMp2027405 | VOL. 383 NO. 18

HEPBURN LEAD THE ADEPT PROGRAM
SLAOUI WAS ON THE BOARD FOR GSK,
& JOINED MODERNA'S BOARD OF
DIRECTORS IN 2017

Moncef Slaoui



Slaoui with GlaxoSmithKline CEO Emma Walmsley (December 2016)

Corporate directorships [edit]

In July 2017, he joined Moderna's Board of Directors.[29]

HTTPS://WWW.NEJM.ORG/DOI/10.1056/NEJMP2027405

Implications for outbreak management

Mike Ryan, MD, the WHO's executive director of emergency programs, told reporters that the WHO welcomes the results and he praised all of the Ebola workers, including the ones working on the infrastructure that allows doctors and nurses to deliver the treatments.

However, he said the tragedy is that not enough people are being treated and not enough people are coming to the hospital. "There are outstanding results for people who seek care early."

Earlier in the outbreak, an ethics committee in the DRC approved the four experimental treatments for compassionate use, and patients at all of the country's Ebola treatment centers have had access to them, along with safety monitoring. However, the formal clinical trial has been under way since November at four treatment centers with the help of the Alliance for International Medical Action (ALIMA), the International Medical Corps (IMC), and Doctors Without Borders (MSF).

At a media telebriefing today, Anthony Fauci, MD, director of the National institute of Allergy and Infectious Diseases (NIAID), said Regeneron was the drug that crossed the efficacy threshold, triggering a pause in the study. And he said the group recommended proceeding with mAb 114, because there were only small differences in the data between the two drugs.

He said the findings of the study are a "ringing endorsement" that ethical and scientifically sound research can be conducted in an outbreak setting.

Jean Jacques Meyumbe Tamfum, PhD, an Ebola expert who was recently appointed to head a group that is now leading the DRC's Ebola response, said he was grateful for the support of international partners, who are working in an extremely difficult setting. "We can no longer say that Ebola virus disease is not curable."



https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs

Leadership

Scientific Advisory Committee

William H. Gates Sr.

Warren Buffett

WATTENDORF JOINED DARPA IN 2010
HE WAS A LEAD PROGENITOR OF THE MONOCLONAL ANTIBODY PROGRAMS AT DARPA

HE NOW WORKS FOR THE BILL AND MELINDA GATES FOUNDATION



Dan Wattendorf

Director, Innovative Technology Solutions



DR. JAMES CROWE

Dr. Crowe's lab delivered an antibody treatment to drugmaker AstraZeneca in a record 25 days. Others funded by the government's pandemic response program also shattered Matt Hepburn's 60-day mark, including biotech company AbCellera, working with Eli Lilly and Regeneron, which was used to treat President Trump.

Dr. James Crowe: This is the new normal. It's gonna be 60 days from here on out.

Well not quite yet - currently, antibodies are grown in a bioreactor like one at this Defense Department Rapid Response Plant in Florida. It'll take three weeks for this to produce 7,500 doses.

Dr. James Crowe: And so-- a lot of scientists are trying to figure out, can this be done faster?

Dr. Crowe has successfully tested a faster way: RNA, the genetic tool DARPA helped pioneer that was used to make the coronavirus vaccine in record time. In the next outbreak -- RNA would allow factories like this to churn out millions of doses a day.

https://www.cbsnews.com/news/last-pandemic-science-military-60-minutes-2021-04-11/

c&en

A small-molecule antiviral discovered by Emory University chemists could soon start human testing against COVID-19, the respiratory disease caused by the novel coronavirus. That's the plan of Ridgeback Biotherapeutics, which licensed the compound, EIDD-2801, from an Emory nonprofit.

EIDD-2801 works similarly to **Gilead Sciences' remdesivir**, an unapproved drug that was developed for the Ebola virus and is being studied in five Phase III trials against COVID-19. Both molecules are nucleoside analogs that metabolize into an active form that blocks RNA polymerase, an essential component of viral replication.

But remdesivir can only be given intravenously, meaning it would be difficult to deploy widely. In contrast, EIDD-2801 can be taken in pill form, says Mark Denison, a coronavirus expert and director of the infectious diseases division at Vanderbilt Medical School. Denison partnered with Emory and researchers at the University of North Carolina to test the compound against coronaviruses.

EIDD-2801 has other promising features. Many **antivirals work** by introducing errors into the viral genome, but, unlike other viruses, coronaviruses can fix some mistakes. In lab experiments,

https://cen.acs.org/biological-chemistry/infectious-disease/Emory-discovered-antiviral-poised-COVID/98/i12



https://advancingcures.org/vic-management-michael-callahan/



Prior Experience

Before coming to MGH, Dr. Callahan was director of the U.S. Agency for International Development (USAID) clinical research programs in Nigeria, DRC (then Zaire) and Ghana. His research focus was congenital malaria, dengue and chikungunya immune convalescent syndrome and filovirus infections (Ebola and Marburg). He has authored over 50 peer-reviewed papers, including 9 U.S. Government guidance documents for infectious disease investments, and 15 chapters in leading textbooks of Medicine and Infectious Diseases, 8 US and international patents for medical advances and has served on over 20 Presidential Commissions or Institute of Medicine Working Groups for Zika, Ebola, Pandemic and Avian Influenza, Biodefense Redirection of FSU Biological Weapons, International drug counterfeiting and the advancement of low cost biologics for low and middle income nations. Dr. Callahan is the recipient of numerous international awards including the Secretary of Defense Award for

Academic Credentials

- BS; Toxicology (1) Microbiology (2) University of Massachusetts at Amherst
- MD; University of Alabama School of Medicine
- Medical Residency & Chief Medical Resident; Tuft-New England Medical Center Hospital
- Fellowship Training; University of Colorado Health Sciences and National Jewish Hospital, Denver, Colorado (Board-certified in Infectious Diseases & Internal Medicine)
- Diplomat: Tropical Medicine and Hygiene: Royal Society of Physicians

Gilead Sciences and supporting researchers and clinicians are working with health authorities from the World Health Organization and in China to establish a placebo-controlled study to determine whether remdesivir is safe and effective in treating 2019-nCoV.

> "This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances."
>
> – Richard Whitley, M.D., UAB Distinguished Professor

"The collaboration between UAB, our colleagues at Southern Research, Vanderbilt University and the University of North Carolina, along with our pharmaceutical partner Gilead Sciences, is indicative of our collaborative approach to respond to outbreaks in real time, and in helping communities worldwide fight 2019-nCoV. This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances," Whitley continued.

Whitley expressed that the potential for mutation of 2019-nCoV means that UAB's AD3C and partners will need to build backup molecules for potential testing and treatment in the near future.

Get the latest COVID-19 information at uab.edu/coronavirus.

UAB is the lead institution for AD3C and research conducted; but the team unifies scientists experienced in virology, viral immunology, pathogenesis, medicinal chemistry and translation to human disease from UAB, University of North Carolina, Vanderbilt University, Emory University, Washington University, The University of Texas Medical Branch, Southern Research, the Emory Institute of Drug Discovery, the University of Colorado, Denver, and Oregon Health & Science University.



HTTPS://WWW.UAB.EDU/NEWS/HEALTH/ITEM/11082-INVESTIGATIONAL-COMPOUND-REMDESIVIR-DEVELOPED-BY-UAB-AND-NIH-RESEARCHERS-BEING-USED-FOR-TREATMENT-OF-NOVEL-CORONAVIRUS

Contract ID:	HHSO100201300018I	**Reference IDV:**	-
Modification Number:	P00008	**Transaction Number:**	-
Award/IDV Type:	IDC Indefinite Delivery Contract	**Action Obligation ($):**	$0.00
Date Signed:	Nov 15, 2021	**Solicitation Date:**	-
Contracting Agency ID:	7505	**Contracting Agency:**	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	**PSC Type:**	P
PSC:	6505	**PSC Description:**	DRUGS AND BIOLOGICALS
NAICS:	325414	**NAICS Description:**	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	**Entity State:**	FL
Entity ZIP Code:	326158726	**Additional Reporting Code:**	-
Additional Reporting Description:	-	**Unique Entity ID:**	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	**Ultimate Parent Legal Business Name:**	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	**CAGE Code:**	3GQS9

Contract ID:	HHSO10033004T	**Reference IDV:**	HHSO100201300018I
Modification Number:	8	**Transaction Number:**	0
Award/IDV Type:	DO Delivery Order	**Action Obligation ($):**	$0.00
Date Signed:	May 18, 2018	**Solicitation Date:**	-
Contracting Agency ID:	7505	**Contracting Agency:**	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	**PSC Type:**	P
PSC:	6505	**PSC Description:**	DRUGS AND BIOLOGICALS
NAICS:	325414	**NAICS Description:**	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	**Entity State:**	FL
Entity ZIP Code:	326158726	**Additional Reporting Code:**	-
Additional Reporting Description:	-	**Unique Entity ID:**	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	**Ultimate Parent Legal Business Name:**	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	**CAGE Code:**	3GQS9

Ology Bioservices /Resilience +BARDA + ASPR 2018-2021 Contracts

https://www.fpds.gov/ezsearch/fpdsportal?s=ICD&indexName=awardfull&templateName=PDF&q=UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+INC.%22+UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+IN

AMERICAN Affairs

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Summer 2021 / Volume V, Number 2

Inside Operation Warp Speed: A New Model for Industrial Policy

by David Adler

Operation Warp Speed[1] (OWS) was launched on May 15, 2020. A partnership between the Departments of Health and Human Services (HHS) and Defense (DoD), other agencies, and the private sector, its goal was to "accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter Covid-19." As a result of OWS, millions of lives were saved from the pandemic.

HTTPS://ARCHIVE.IS/L3NIV

OWS and Vaccine Development

Slaoui and Hepburn published an article in the *New England Journal of Medicine* in October 2020 in which they explained OWS's strategy for vaccine development: "We sought to build a diverse project portfolio that includes two vaccine candidates based on each of the four platform technologies."[9] Core to OWS's acceleration strategy was to run vaccine development processes in parallel rather than sequentially. Almost from the outset, OWS took on the unprecedented financial risk of funding and scaling up manufacturing efforts while the vaccine candidates were still in clinical trials.

To choose from over a hundred vaccine candidates, OWS used "down select," according to Hepburn, meaning whittling down the list using objective criteria. "The goal was never to try to pick one type of vaccine technology, let alone one company, but instead to keep the portfolio diverse. This was very deliberate given the many unknowns," he says. Vaccine candidates had to use one of the three platform technologies deemed most promising. They were further selected on the basis of clinical trial data and other formalized criteria, including their potential for scalability in manufacturing. In the end, three vaccine platforms, and two companies per platform, were targeted: (1) mRNA: Moderna, Pfizer/BioNTech; (2) replication-defective live-vector platform: AstraZeneca, Janssen; (3) recombinant-subunit-adjuvanted protein: Novavax, Sanofi/GSK.

HTTPS://ARCHIVE.IS/L3NIV

OWS heavily invested in R&D for these vaccine candidates. Pfizer was an outlier in that OWS did not fund development or manufacturing, but it did place a roughly a $2 billion order for a hundred million doses, contingent upon FDA approval or authorization of the vaccine. Pfizer's CEO said the reason for this structuring was to "liberate" the company from government bureaucracy. Another unstated but possible motive was to immunize Pfizer's intellectual property from public claims related to federally funded research. Notably, moreover, Pfizer's partner BioNTech received $445 million in funding for development and scale-up manufacturing from the German government.[12]

Moderna designed its vaccine in just two days, demonstrating the power of mRNA technology. It produced an actual vaccine that could be tested on humans in sixty-three days. Nevertheless, Moderna, unlike Pfizer, lacked deep expertise at running clinical trials, and faced the problem of too few minority volunteers. Here the NIH stepped in to help. OWS pursued a strategy of running clinical trials concurrently rather than sequentially, saving significant time.

Dr. Michael Callahan, an infectious disease specialist at Massachusetts General Hospital and Harvard Medical School, explains just how radical these results were, including the novel technology and development efforts that led to them: "mRNA-based protein expression is the most recent interesting American invention," Callahan says. "Warp Speed could not have happened if the technology had not been developed to move this quickly. We got very lucky with mRNA." With mRNA, scientists only need to know the sequence of the virus to design a vaccine. Sequence data was provided by the Chinese in the first week of January 2020. China's capabilities in this area are comparable to or better than America's.

Callahan's academic bio doesn't convey the depth of his expertise. Callahan previously oversaw DARPA's biodefense therapeutics portfolio, the "Accelerated Manufacture of Pharmaceuticals" (AMP) program, whose goal was to radically accelerate the manufacturing of protein vaccines, and sister programs "7 Day Biodefense" and "Prophecy" (to predict virus evolution). Callahan coled the world's largest international medical evacuation from a hot zone, the repatriation of nearly four hundred Americans from the Covid-19-plagued *Diamond Princess* cruise ship, and emergency care of infected passengers on the *Grand Princess* cruise. He was then recruited as special adviser on Covid-19 to the assistant secretary of preparedness and response (ASPR), Robert Kadlec.

But there are potential risks, even controversies, related to OTs. They bring reduced transparency, and some exemptions from regulations designed to protect taxpayers. Specifically, the concern around OWS is that OTs might have allowed pharma companies to circumvent the Bayh-Dole Act,[17] which provides the public with rights in intellectual property arising out of federally funded research, including march-in rights.[18]

EUA. Emergency Use Authorization (EUA) is a mechanism to allow use of medical products without full FDA approval during a health emergency, such as a pandemic. Traditional FDA approval for a vaccine can take years, whereas an EUA is much quicker, though it still involves rigorous evaluation by the FDA. As the FDA notes, "efforts to speed vaccine development to address the ongoing Covid-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety."[19]

The GAO, however, was slightly critical in its report assessing the use of EUAs during the pandemic. Its study in no way argued that the authorized medicines weren't safe, but rather that "the FDA does not uniformly disclose its scientific review of safety and effectiveness data for EUAs," as it does for traditional approvals.[20]

HTTPS://ARCHIVE.IS/L3NIV

Someone still had to make hundreds of millions of doses of mRNA, however, and very few companies had this expertise. Moderna already operated an existing advanced biotech manufacturing facility, but more production capacity was required. Moderna partnered with the contract manufacturer Lonza in May 2020,[27] long before its vaccine received an EUA. With funding provided by OWS through BARDA, the companies established mRNA manufacturing lines at Lonza's factories in the United States and Switzerland.

HTTPS://ARCHIVE.IS/L3NIV

Admiral Brett P. Giroir, MD, assistant secretary of HHS, took on the role of coordinating Covid-19 diagnostic testing in March 2020. He explains some of the challenges facing the United States: "We didn't have a stockpile of tests or basic materials, and very little domestic manufacturing capacity. We had to scramble to import basic materials like swabs and pipette tips while we jump-started domestic production. There were no rapid tests, only PCR tests that required sophisticated laboratories." Admiral Giroir began flying in one 747 a week filled just with swabs and similar basic materials from Europe.

Admiral Giroir, who earlier had directed the Defense Sciences Office at DARPA, implemented private-public partnerships to scale the manufacturing of tests. The government invested billions of dollars to build domestic test manufacturing capacity. By June 2020, the United States was testing five hundred thousand people daily.

In terms of vaccine production, OWS had been working with companies to scale up manufacturing almost from inception, when vaccine candidates were still only in preclinical trials. Slaoui and Hepburn, in their *NEJM* article, described some of the ways OWS offered technical support for the rapid scaling of manufacturing:

> To ensure that industrial processes are set, running, and validated for FDA inspection when phase 3 trials end, OWS is supporting facility building or refurbishing, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate.[26]

Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.

These DARPA programs are part of a broader biodefense effort to address threats that include naturally occurring epidemics, as well as accidental biological exposures, biowarfare, and bioterrorism. The nation's biodefense enterprise is distributed, spanning multiple departments and agencies with different missions, making preparing for and responding to a diverse and evolving set of biological threats challenging. In 2016, Congress directed the Secretaries of Health and Human Services (HHS), Defense, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan (P.L. 114-328, Section 1086). Issued in September 2018, the *National Biodefense Strategy* (with an implementation plan in Annex I) calls for the integration of biodefense R&D into federal planning, emphasizing the development of procedures and policies for interagency coordination of R&D efforts associated with responding to a biological incident. While the plan also calls for the sustainment of a robust national science and technology base to support biodefense, it does not articulate a need for interagency R&D planning and coordination. In 2015, the Blue Ribbon Study Panel on Biodefense, now the Bipartisan Commission on Biodefense, highlighted military-civilian collaboration in biological R&D as one of many issues that "deserve more congressional oversight."

The Biological Technologies Office currently supports a number of programs that address pandemics. Since the emergence of COVID-19, DARPA has shifted the efforts of many of these programs to focus specifically on the coronavirus pandemic. According to DARPA,

> There is currently a mismatch between the rapidity at which biological threats can emerge and proliferate and the response time for developing and deploying effective medical countermeasures.… Cognizant of the need for speed, DARPA began aggressively pursuing medical countermeasures research more than a decade ago with a focus on developing generalizable, virus-agnostic technologies that can address whatever threat emerges, rather than building a collection of one-off solutions.

Examples of current DARPA investments include the Pandemic Prevention Platform (P3) program, whose goal is to develop methods "capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat." Awardees of the P3 program have been applying the results of their work to COVID-19. For example, a COVID-19 antibody treatment developed with support from DARPA by AbCellera Biologics, in partnership with Eli Lilly and the National Institutes of Health (NIH) Vaccine Research Center, began human clinical trials in June 2020.

Additionally, an awardee from DARPA's Epigenetic Characterization and Observation (ECHO) program, Fluidigm, in collaboration with a consortium of medical schools, is developing an early detection test for SARS-CoV-2, the novel virus that causes COVID-19.

In its role as advisor to the Secretary of HHS, the National Biodefense Science Board (NBSB), stated that

> R&D for technologies, platforms, and systems to develop new MCM [medical countermeasures] against Disease X in 28 days from the recognition of the outbreak, which NBSB recommends as [a]

Nathan Wolfe

3 languages

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From Wikipedia, the free encyclopedia

Nathan Daniel Wolfe (born 24 August 1970) is an American virologist. He was the founder (in 2007) and director of Global Viral[1] and the Lorry I. Lokey Visiting Professor in Human Biology at Stanford University.

Career [edit]

Wolfe spent over eight years conducting biomedical research in both sub-Saharan Africa and Southeast Asia. He is also the founder of Metabiota, which offers both governmental and corporate services for biological threat evaluation and management. He serves on the editorial board of *EcoHealth* and *Scientific American* and is a member of DARPA's Defense Science Research Council. His laboratory was among the first to discover and describe the Simian foamy virus.[2]

In 2008, he warned that the world was not ready for a pandemic.[3]

In 2011, his book *The Viral Storm: The Dawn of a New Pandemic Age*[4] was short-listed for the Winton Prize.[5]

As reported in a *Wired* feature in 2020, Wolfe worked with the German insurance firm Munich Re to offer major corporate leaders pandemic policies, which were not purchased; a stark reality during the ensuing COVID-19 pandemic.[6]

Awards [edit]

Wolfe has been awarded more than $40 million in funding from a diverse array of sources including the U.S. Department of Defense, Google.org, the National Institutes of Health, the Skoll Foundation, the Bill & Melinda Gates Foundation and the National Geographic Society.[7]

- Fulbright fellowship recipient (1997)
- National Geographic Emerging Explorer (2004)[2]
- NIH Director's Pioneer Award (2005)
- *Popular Science*: "Brilliant 10" (2006)
- *Rolling Stone*: "Top 100 Agents of Change" (2009)
- World Economic Forum's Young Global Leaders (2010)

Nathan D. Wolfe



Wolfe in 2011

Born	August 24, 1970 (age 53) Detroit, Michigan, U.S.
Citizenship	United States
Alma mater	Stanford, Harvard
Scientific career	
Fields	Virology
Institutions	Stanford, UCLA

Nathan Wolfe-

Ecohealth Alliance Collaborator with DARPA

Richard Hatchett

1 language

Article Talk Read Edit View history Tools

From Wikipedia, the free encyclopedia

(Redirected from Richard J. Hatchett)

Richard Hatchett is an American oncologist[1] and epidemiologist who has been serving as chief executive officer of the Coalition for Epidemic Preparedness Innovations (CEPI) in Oslo and London since 2017.[2][3] He was awarded the Secretary of Health and Human Services's Award for Distinguished Service.[4]



Dr Richard J. Hatchett (2011)

Early life and education [edit]

Hatchett grew up in Alabama.[5] He graduated from Vanderbilt University and Vanderbilt University School of Medicine.[6] He completed an internship and residency in Internal Medicine at New York Hospital – Cornell Medical Center, and a fellowship in Medical Oncology at the Duke University Hospital.[7] He was also a research associate at the National Heart & Lung Institute at Imperial College London and spent three months in northeast Gabon investigating three closely related Ebola outbreaks.[8]

Richard Hatchett:

Vanderbilt Univ,
Cornell, & Duke

Suspected Former CIA
Former BARDA
Current CEO at CEPI

Richard Hatchett:

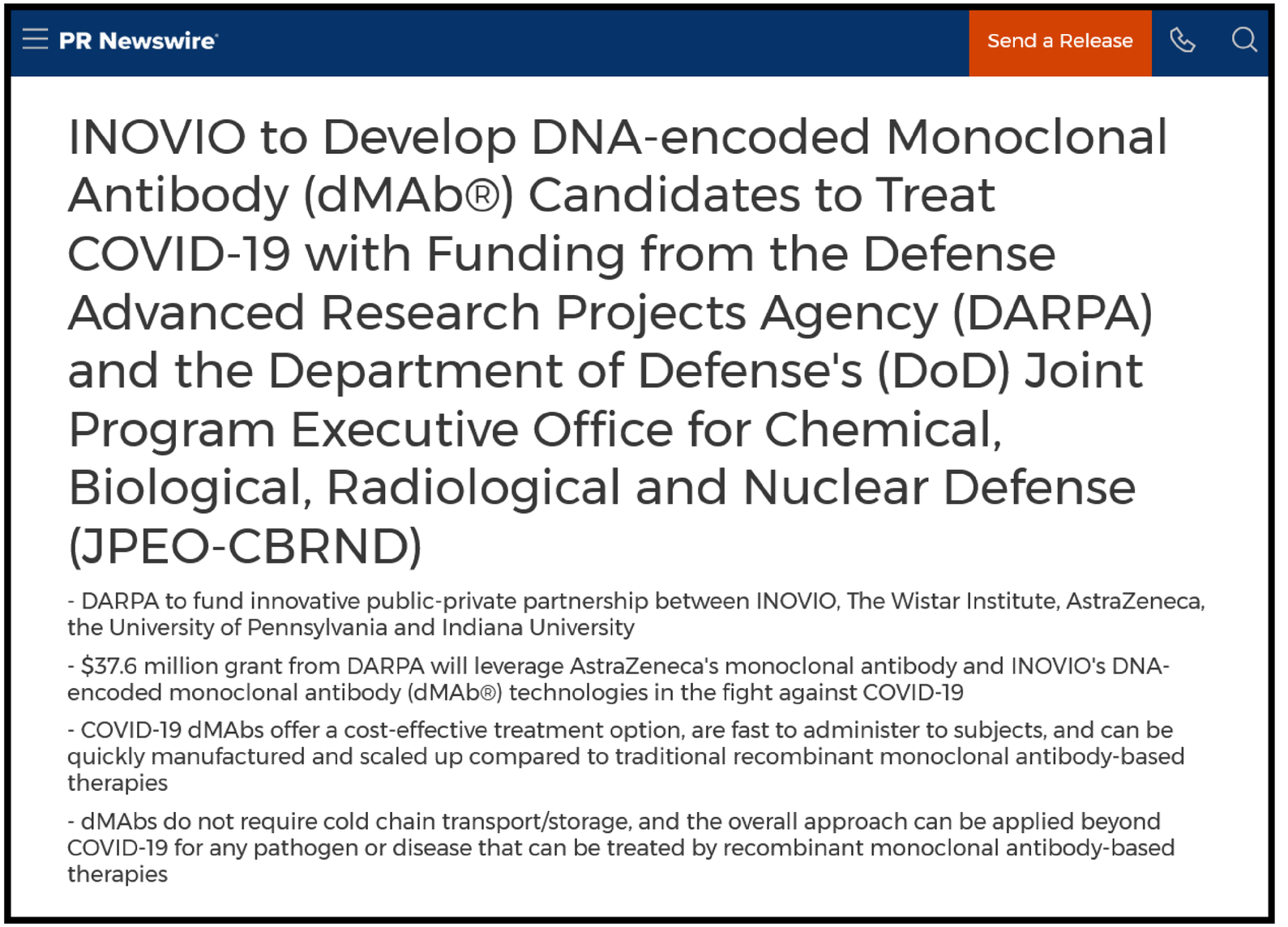
Hatchett was the Chief Medical Officer and deputy director of the United States Biomedical Advanced Research and Development Authority (BARDA) from 2011 to 2016 before becoming the organization's acting Director in 2016.[20] At BARDA, he oversaw programs to develop medical countermeasures against chemical, biological, radiological and nuclear threats, pandemic influenza, and emerging infectious diseases and led or helped lead the development of vaccines, therapeutics and diagnostics for a number of emerging viruses, including the H3N2v and H7N9 influenza viruses, MERS, Ebola and Zika.[21]

CEO of CEPI, 2017–present [edit]

In 2017, Hatchett was appointed as CEO of the Coalition for Epidemic Preparedness Innovations, succeeding interim CEO John-Arne Røttingen.[22] In May 2020, amid the COVID-19 pandemic, he was appointed to the expert advisory group for the UK Government's Vaccine Task Force.[23] When the UK held the rotating presidency of the Group of Seven (G7) in 2021, the government also appointed him to serve as a member of the Pandemic Preparedness Partnership, chaired by Patrick Vallance.[24][25]

Under Hatchett's leadership, CEPI funded early development of COVID-19 candidate vaccines. CEPI also teamed up with the African Union to fund African vaccine production.[26][27] Together with Seth Berkley, he developed the concept for COVAX in early 2020.[28] CEPI is organizing a 2022 Covid summit.[29][30]

In March 2020, Hatchett warned about COVID-19.[31] He does not think Intellectual property rights significantly contribute to vaccine shortages.[32][33] He is concerned about supply chain problems,[34][35] and export controls.[36]



mhttps://www.prnewswire.com/news-releases/inovio-to-develop-dna-encoded-monoclonal-antibody-dmab-candidates-to-treat-covid-19-with-funding-from-the-defense-advanced-research-projects-agency-darpa-and-the-department-of-defenses-dod-joint-program-executive-office-fo-301192706.html

Elsevier

Med (N Y). 2022 Mar 11; 3(3): 188–203.e4. Published online 2022 Feb 3. doi: 10.1016/j.medj.2022.01.004

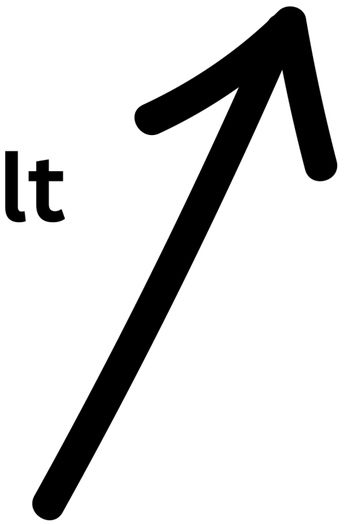
PMCID: PMC8810411 | PMID: 35132398

A combination of two human neutralizing antibodies prevents SARS-CoV-2 infection in cynomolgus macaques

Ronald R. Cobb,[1,15] Joseph Nkolola,[2,15] Pavlo Gilchuk,[3,15] Abishek Chandrashekar,[2] Jingyou Yu,[2] Robert V. House,[4] Christopher G. Earnhart,[5] Nicole M. Dorsey,[5] Svetlana A. Hopkins,[6] Doris M. Snow,[4] Rita E. Chen,[7,8] Laura A. VanBlargan,[7] Manuel Hechenblaickner,[1] Brian Hoppe,[1] Laura Collins,[1] Milan T. Tomic,[9] Genevieve H. Nonet,[9] Kyal Hackett,[4] James C. Slaughter,[10] Mark G. Lewis,[11] Hanne Andersen,[11] Anthony Cook,[11] Michael S. Diamond,[7,8,12] Robert H. Carnahan,[3,13] Dan H. Barouch,[2,*] and James E. Crowe, Jr.[3,13,14,16,**]

2022

Crowe of Vanderbilt alongside the JPEO-CBRND & Ology Bioservices



PMC PubMed Central®

Kyal Hackett,[4] James C. Slaughter,[10] Mark G. Lewis,[11] Hanne Andersen,[11] Anthony Cook,[11] Michael S. Diamond,[7,8,12] Robert H. Carnahan,[3,13] Dan H. Barouch,[2,*] and James E. Crowe, Jr.[3,13,14,16,**]

Author information ▸ Article notes ▸ Copyright and License information PMC Disclaimer

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[3]Vanderbilt Vaccine Center, Vanderbilt University Medical Center, Nashville, TN 37232, USA
[4]Ology Bioservices, Frederick, MD 21701, USA
[5]Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, US Department of Defense, Frederick, MD 21703, USA
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[11]Bioqual, Inc., Rockville, MD 20850, USA
[12]Department of Molecular Microbiology, Washington University School of Medicine, St. Louis, MO 63110, USA
[13]Department of Pediatrics, Vanderbilt University Medical Center, Nashville, TN 37232, USA
[14]Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN 37232, USA
*Corresponding author

Feedback


IQT
IN-Q-TEL
The Cash Cow behind the CIA

Thetus
AI-ENABLED APPLICATIONS

Palantir
AI-ENABLED APPLICATIONS

Cassatt
AI-ENABLING PLATFOR

Metabiota
AI-ENABLED APPLICATIONS, BIOTECHNOLOGY

The Unseen Conflict: Strategic Technology Com

February 2020

Watch Chris Darby testify before the U.S. House ee on Intelligen
Subcommittee on Strategic Technologies and Ad uary 2020 hear
"Emerging Technologies and National Security: F nce Community fo
Success." Read his Statement for the Record, The Unseen Conflict: Strategic Technology Competition.

Investment and Innovation in U.S. Intelligence

April 2019

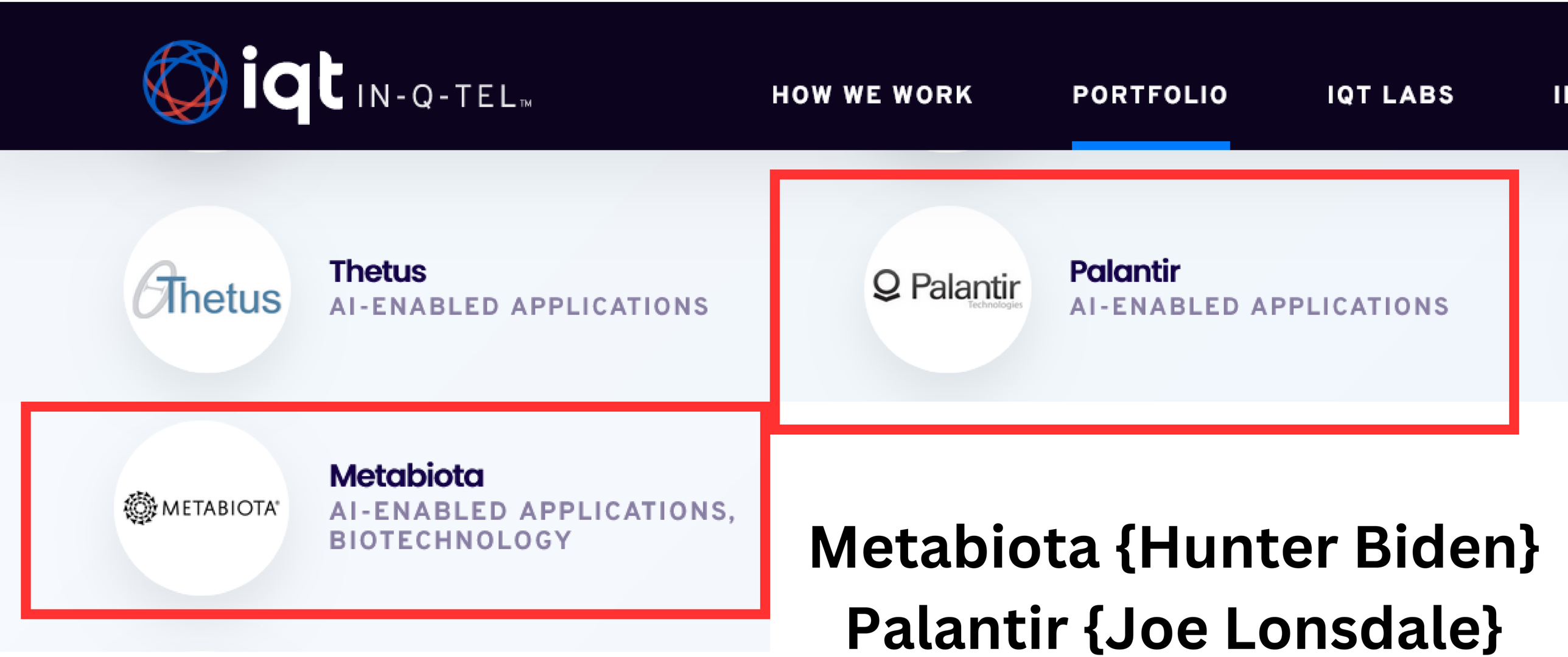
Listen to Chris Darby's interview with Michael Morell about investment and innovation in th
U.S. Intelligence Community on the *Intelligence Matters Podcast*.

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In-Q-Tel Investments of Concern

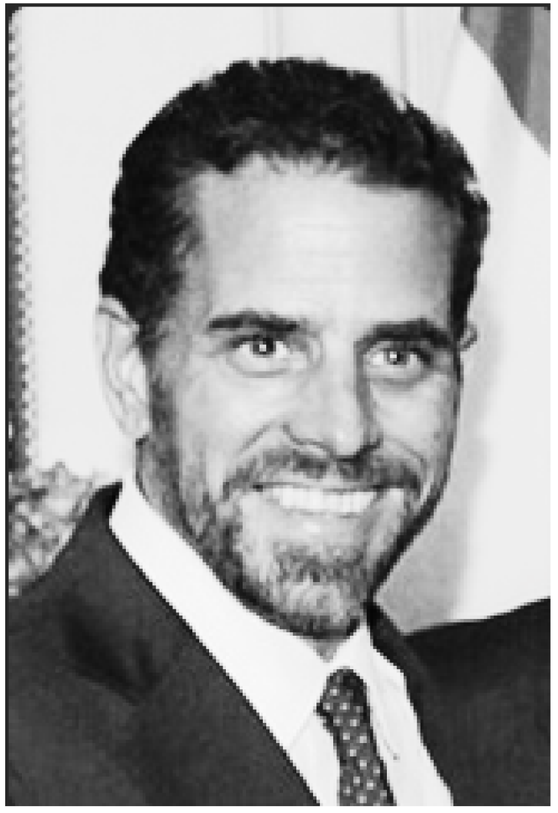


Metabiota {Hunter Biden}

Palantir {Joe Lonsdale}

Munich Re & In-Q-Tel Se… Metabiota to Gain Deepe… Insights into Epidemic Ris… and Global Preparedness for Infectious Diseases

AUG. 22, 2017



NEW YORK POST
AUGUST 21, 2023

Rosemont Seneca Technology Partners invested $500,000 in the San Francisco pathogen research company Metabiota and raised millions more through firms that included Goldman Sachs, according to the e-mails found on the computer, which was abandoned at a Delaware repair shop in April 2019 as Joe Biden ran for president.

Hunter introduced Metabiota to officials at Burisma, the Ukrainian gas company where he was a board member, for a “science project” involving biolabs in Ukraine, the e-mails show.

METABIOTA®

A memo from a Metabiota official to the then-vice president’s son in 2014 said the company could “assert Ukraine’s cultural and economic independence from Russia.”

Project Impact: 'Disease intelligence' and how the CIA traced epidemics out of Cold War Asia

When a new flu strain emerged in Hong Kong, a CIA program "went global."

By Lee Ferran
June 20, 2020, 4:00 AM



Darrell M. Blocker, a former senior CIA officer who was head of the agency's Africa Division during the Ebola crisis in 2014, said the CIA's mission in disease intelligence is similar today as it was more than a half-century ago and is twofold: Uncovering what's really happening on the ground in countries during epidemics that don't like to share that information and attempting to predict what effect it could have on U.S. interests in the region.

"There's a side to the [disease] research they don't want people to know about. That's where the intelligence comes in," said Blocker, now an ABC News contributor. A spokesperson for the CIA declined to comment for this report.

Blocker said now the U.S. intelligence community can call on its vast, 17-organization-strong apparatus to assess what a disease is doing and how local governments are reacting. But in the mid-1960s, a young CIA was only then starting to appreciate the value of disease intelligence. According to the 1972 declassified CIA article titled "Intelligence Implications of Disease," it began with Project IMPACT.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

United States Agency for International Development

文 46 languag

Article Talk Read Edit View history To

From Wikipedia, the free encyclopedia

The **United States Agency for International Development** (**USAID**) is an independent agency of the U.S. federal government that is primarily responsible for administering civilian foreign aid and development assistance. With a budget of over $27 billion, USAID is one of the largest official aid agencies in the world and accounts for more than half of all U.S. foreign assistance—the highest in the world in absolute dollar terms.

Congress passed the Foreign Assistance Act on September 4, 1961, which reorganized U.S. foreign assistance programs and mandated the creation of an agency to administer economic aid. USAID was subsequently established by the executive order of President John F. Kennedy, who sought to unite several existing foreign assistance organizations and programs under one agency.[4] USAID became the first U.S. foreign assistance organization whose primary focus was long-term

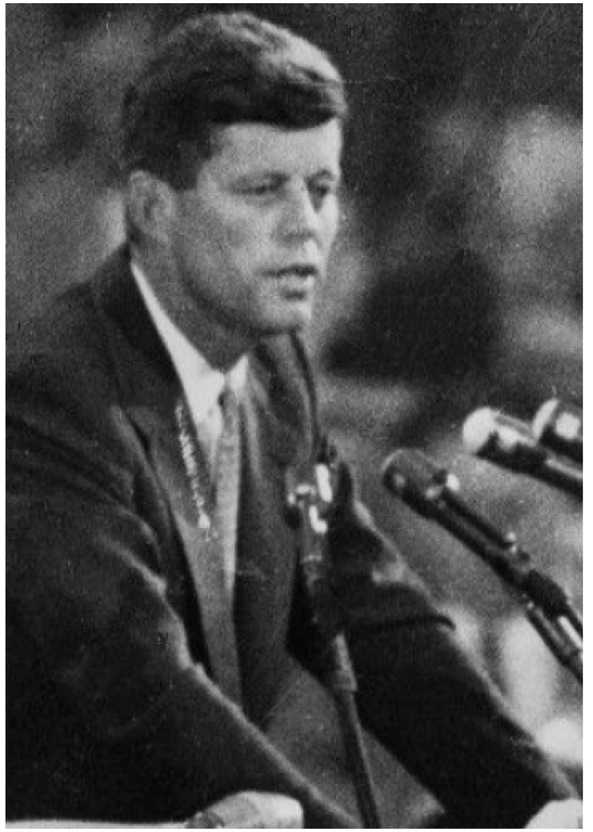
Histor

History of USAID

United States Agency for International Development

Seal of USAID

Agency overview	
Formed	November 3, 1961; 61 years ago
Preceding agency	International Cooperation Administration
Headquarters	Ronald Reagan Building Washington, D.C., U.S.
Motto	"From the American people"
Employees	10,235 employees (FY 2016)[1]
Annual budget	$27.2 billion (FY 2016 Budgetary Resources)[2]



USAID
FROM THE AMERICAN PEOPLE

CIA

+

USAID

What connection to the PREDICT program is there with the CIA?

↘ PERPLEXITY

There is a connection between the PREDICT program and the CIA, as the program has been accused of having ties to the CIA. The PREDICT program is part of the USAID's Emerging Pandemic Threats program and is led by the UC Davis One Health Institute [1]. The program seeks to identify new emerging infectious diseases that could become a threat to human health by focusing on wildlife that are most likely to carry zoonotic diseases [2]. However, in 2020, the program was shut down by the Trump administration, and it was reported that the program had been accused of having ties to the CIA. The accusations were based on the fact that the PREDICT program had worked with the Defense Threat Reduction Agency, which is part of the Department of Defense and has been known to work with the CIA. However, the PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health.

USAID
FROM THE AMERICAN PEOPLE

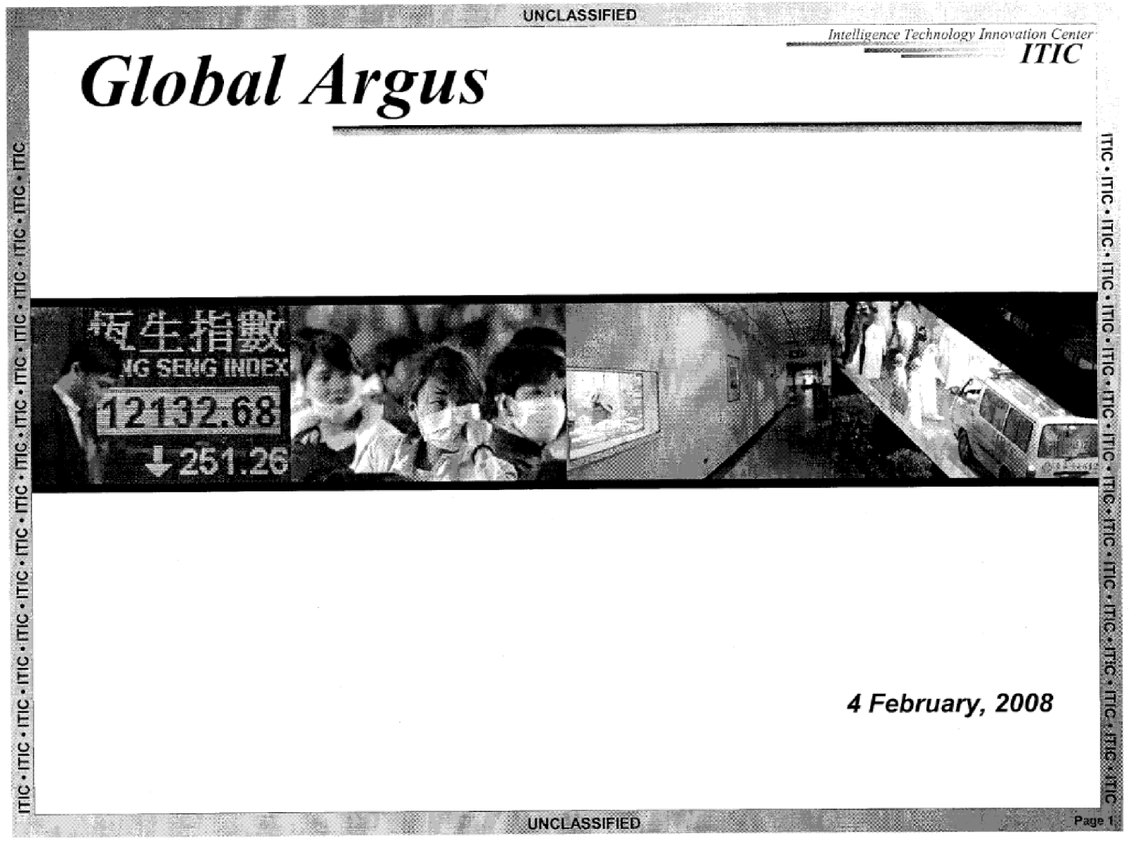
been known to work with the CIA [1]. The PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health [2]. While the CIA has been involved in disease intelligence and analysis dedicated to uncovering epidemics, such as Project IMPACT in the mid-1960s [3], there is no evidence that the CIA has been directly involved in the PREDICT program.

of this massive epidemic. Whether the ensuing decline of the disease was due to the extensive use of sulfadiazine or to the normal decline of the epidemic cycle was never ascertained. It was followed by other predicted disease outbreaks (i.e., hepatitis, measles), and a recurrence of a much less severe meningitis epidemic in the winter of 1967–1968. As a postscript, China's failure to prevent and control the spread of diseases was viewed by the USSR as a fundamental weakness of the Chinese health services and the Soviet Ministry of Health abruptly rescinded the 1960 Sino-Soviet agreement on mutual abolition of vaccination requirements for travellers between these countries.

Project IMPACT went global in the summer of 1968 when a new strain of influenza rolled out of China and within a short period of time affected one out of every four persons in the world. The strain was not an unusually lethal one but it was only by chance that it was not. Again, various Agency sources provided the first indication of the beginning of this worldwide pandemic when the disease moved from China via travellers to Hong Kong in late June. An estimated 500,000 cases resulted in Hong Kong alone including 30 percent of the personnel at the American Embassy. At this time a unique opportunity was available to review statistical data on influenza (a program to computerize disease information to derive trends, cycles and predictions had already been initiated under a CIA Project called BLACKFLAG); the current epidemic in Hong Kong was causing the highest incidence since the first Asian Type A2 epidemic of 1957. While the epidemic appeared to be progressing in a new way, initial

SECRET

Operation BLACKFLAG



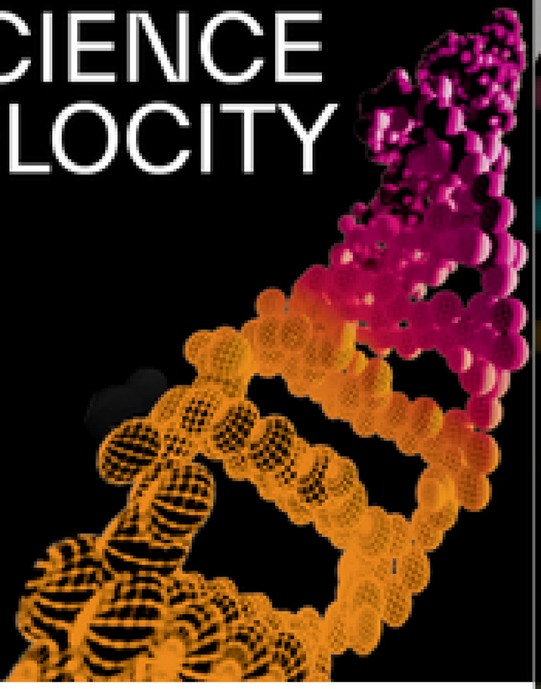
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WHERE SCIENCE MEETS VELOCITY

June 5-8, 2023
Booth #: 385

Boston, MA



Would you like to meet at BIO2023?

USAID + CIA History

How has USAID's alleged political meddling changed over time

PERPLEXITY

USAID's alleged political meddling has changed over time. Here are some examples:

1. In 2012, the Russian Foreign Ministry accused USAID of meddling in domestic politics [1]. USAID was subsequently shut down in Russia [2].
2. In Bolivia, state news agencies blamed USAID for "alleged political interference with peasant unions and social organizations" [3].
3. Throughout the 1960s and 1970s, USAID often partnered with the CIA's now-shuttered Office of Public Safety, a department beset by allegations that it trained foreign police in "terror and torture techniques" and encouraged official brutality [4].
4. In recent years, USAID's alleged political meddling has been more subtle. A WikiLeaks cable released in 2013 outlined the US government's plan to use USAID to create a social media platform in Cuba to undermine the government [4].
5. USAID has been involved in electoral assistance, which helps strengthen a democratic culture that increases resilience to malign foreign influence [5].
6. Some foreign governments have embraced the narrative that USAID acts as a cover for US intelligence programs [4] [6].

EHA + DHS

What specific research projects has EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction

PERPLEXITY

The search results do not provide specific information on the research projects that EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction. However, according to a news article, the Defense Threat Reduction Agency (DTRA) began awarding funding to EcoHealth Alliance for a work program labeled "Scientific Research – Combating Weapons of Mass Destruction" beginning in fiscal year 2014 [1]. The DTRA describes its mission as "to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks" [1]. The funding from the DTRA was part of the Department of Defense's efforts to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks [1].

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Metabiota Gains Government Momentum with Black & Veatch Sub-Contracts for Defense Threat Reduction Programs

PRESS RELEASE PR Newswire

Aug. 8, 2018, 09:00 AM

SHARE

SAN FRANCISCO, Aug. 8, 2018 /PRNewswire-PRWeb/ -- Today, **Metabiota**, the pioneer in epidemic risk modeling, announced it has been awarded a subcontract from Black & Veatch (B&V) to support the U.S. Defense Threat Reduction Agency's (DTRA) Cooperative Biological Engagement Program (CBEP) in Iraq under the Biological Threat Reduction Integrating Contract (BTRIC). Metabiota has also partnered with B&V on DTRA's recently awarded Cooperative Threat Reduction Integrating Contract (CTRIC) III with an Indefinite Delivery/Indefinite Quantity (ID/IQ) contract ceiling of $970M.

Your Market View

NAME	PRICE	+/-	%	DATE
TSLA	159.97	-0.34	-0.21	Official Close 5/2/2023
AAPL	168.60	0.06	0.04	Official Close 5/2/2023
MSFT	305.95	0.54	0.18	Official Close 5/2/2023
NFLX	317.38	-0.18	-0.06	Official Close 5/2/2023
SPOT	136.10	-0.40	-0.29	Official Close 5/2/2023

According to published government figures, the EHA received direct funding totalling $46.15 million from the US Department of Defence from 2008 onwards and $41.85 million of this came from the Defense Threat Reduction Agency (DTRA).

The total awarded amount, from 155 transactions involving agencies and sub-agencies, is stated to be $80.1 million.

Direct funding from the USAID is put at $11.17 million, but this doesn't include funds provided for subcontracted work, for instance for the PREDICT project.

The University of California at Davis is a major PREDICT grantee and the EHA is one of the university's main sub-grantees.

3/24/2023

Resilience Approved for $410M Financin from the Department of Defense, in Partnership with the Development Finan Corporation, to Establish Resilient Biomanufacturing Capacity

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RESILIENCE APPROVED FOR $410M FINANCING FROM THE DEPARTMENT OF DEFENSE, IN PARTNERSHIP WITH THE DEVELOPMENT FINANCE CORPORATION, TO ESTABLISH RESILIENT BIOMANUFACTURING CAPACITY

03/24/2023

Financing focused on domestic biomanufacturing capacity and capabilities for biologics, vaccines, and nucleic acids

SAN DIEGO--(BUSINESS WIRE)-- National Resilience, Inc. (Resilience), a technology-focused biomanufacturing company dedicated to broadening access to complex medicines, today announced that it has signed a finance agreement for $410 million in long-term loan financing from the U.S. Department of Defense (DoD), working with the U.S. International Development Finance Corporation (DFC).

The loan financing will support Resilience's mission to establish significant domestic, end-to-end biomanufacturing capacity and capabilities for biologics (antibodies, proteins, multi-specifics), vaccines, and nucleic acids (including mRNA). This expanded capacity, together with existing technology and capabilities across Resilience's biomanufacturing network, will help secure the nation's supply chain for vaccines and critical medicines, bolster pandemic preparedness and response, and help address a critical advanced manufacturing infrastructure shortage revealed by the COVID-19 pandemic. Part of the financing will support the implementation of innovative manufacturing platforms and technologies that aim to reduce cost, strengthen the domestic supply chain, and increase the speed of vaccine supply.

The long-term financing also strengthens Resilience's ability to deliver the highest quality products to patients and to the 50-plus commercial customers that utilize its nearly two million square feet of end-to-end drug development capacity and solutions that span process and analytical development and GMP biomanufacturing across multiple therapeutic modalities. With this support, Resilience will be able to manufacture a billion doses of vaccines within its manufacturing network in the United States and will continue to partner with biotech and biopharma innovators across the drug development life cycle.

MEMO: Ukraine Science

Subject: MEMO: Ukraine Science
From: Mary Guttieri [redacted]
Date: 4/4/14, 6:14 AM
To: [redacted]
CC: [redacted]

Hi Hunter,

I hope you enjoyed a smooth flight across the pond and that this finds you and your wife enjoying a wonderful Friday in beautiful Lake Como!

Thanks so much for taking time out of your intense schedule to meet with Kathy and I on Tuesday. We very much enjoyed our discussion. As promised, i've prepared the attached memo, which provides an overview of Metabiota, our engagement in Ukraine, and how we can potentially leverage our team, networks, and concepts to assert Ukraine's cultural and economic independence from Russia and continued integration into Western society. The pdf comprises English and Ukrainian versions of the document.

Please let me know if you have any questions or require clarification. We look forward to hearing the outcome of your discussions on this topic.

Wishing you successful meetings and a great visit!

Best regards,
Mary

Mary C. Guttieri, PhD

Vice President, Science & Technology Administration

BTRIC S&T Program Manager

Metabiota, Inc.

Mobile: [redacted] *| mguttieri@metabiota.com*

Hunter Biden Laptop Emails about Metabiota + Ukraine + Russia

Subject: IC Materials
From: John DeLoche
Date: 3/10/14, 2:36 AM
To: Hunter Biden, Devon Archer, Neil Callahan, William Lee <will@rstp.com>

IC Committee,

In the interest of establishing a clear process for our investment approvals I wanted to give you a preview of the agenda for the first IC Committee call, which I hope we can do on our weekly call tmw. In the future we will plan to have full memos distributed to the committee for each deal the friday before the Monday committee meeting. Apologies we were not able to put together a memo for Metabiota given our front end loading of Lyft. We will put one together for Metabiota shortly.

We have three deals to discuss tmw.

The first is an increase in our investment in Metabiota by $250k. Docs are attached. They raised about $2.4mm of which we represent $500k (250k from the first investment plus this one). They intended to raise a max of $1.6mm but it was oversubscribed. They way to think about this one is that Palantir is the to the CIA what Metabiota is to the USDA. The company's plan is to take advantage of the current fundraising climate and start raising a series A as soon as this series seed closes. They hope to raise another $15mm at at least $80mm pre which would be a nice 5x mark-up to our investment. We are planning to show it to Founders Fund, Andreessen and Google Ventures (among others) as potential leads.

The second is an investment in Lyft (doc attached)

The third is an increase in our investment in Counsyl. Goldman is going to committee on Lyft and Counsyl on Tuesday.

Best,

John

John DeLoche
Managing Director
Rosemont Seneca Technology Partners
333 Bush Street, 21st Floor
San Francisco, CA 94104
office:
mobile

Hunter Biden Laptop Emails about Metabiota + Ukraine, Palantir + the CIA

Subject: Re: Metabiota DD
From: Rob Walker
Date: 10/10/14, 12:07 AM
To: John DeLoche
CC: Devon Archer, Hunter Biden, Eric Schwerin, Neil Callahan, William Lee, Rob Walker

I am going to have a friend reach out to DoD on the down low.

On Oct 9, 2014 5:49 PM, "John DeLoche" wrote:

> Guys,
>
> Is there anyone we can call in DC to get a sense of how Legit Metiabiota is viewed within the various government agencies? We want to make sure we thoroughly do our diligence here, especially as Goldman and now Morgan Stanley will be doing diligence on the fund and Metabiota towards investing in both.
>
> Additionally, who have we introduced them do in DC? Can you please provide a list of the various folks within Cornerstone as well as outside the firm where we have made intros? This data will go in our investment memo which we are trying to complete and get to potential LPs by Tuesday.
>
> Will and I met with Nathan on Tuesday and he said they plan to retain Cornerstone btw which is great news so they have come around on that front. We are meeting again with them today and tomorrow to discuss terms of the Series A.
>
> Thanks for the help and input.
>
> Best,
>
> John
>
> John DeLoche
> *Co-founder and Managing Director*
> Rosemont Seneca Technology Partners
> 333 Bush Street, 21st Floor
> San Francisco, CA 94104
> office:
> mobile

Hunter Biden Laptop Emails about Metabiota + DoD

Tara O'Toole

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From Wikipedia, the free encyclopedia

Tara O'Toole served as the Under Secretary of Homeland Security for Science and Technology from 2009 to 2013. She is currently a senior fellow and executive vice president at In-Q-Tel.[1]

Background [edit]

Prior to her confirmation as Under Secretary (November 4, 2009), O'Toole founded, and served as chief executive officer and director of, the Center for Biosecurity at the University of Pittsburgh Medical Center. Concurrently, she was a Professor of Medicine and of Public Health at the University of Pittsburgh. She stepped down from her position as Under Secretary on September 23, 2013

Tara O'Toole	
Personal details	
Education	Vassar College (BA) George Washington University (MD) Johns Hopkins University (MPH)

Former Director



Tara O'Toole, MD, MPH



FBI Director Christopher Wray said in February the pandemic "most likely" resulted from a potential lab leak in Wuhan, even while U.S. intelligence agencies remained divided on the cause, with none having reached a conclusion with a high degree of confidence.

RESILIENCE TO MANUFACTURE MRNA FOR MODERNA'S COVID-19 VACCINE

SEPTEMBER, 08, 2021

DOWNLOAD

SAN DIEGO & CAMBRIDGE, Mass.--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company seeking to build the world's most advanced biopharmaceutical manufacturing ecosystem, and Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) medicines, today announced an agreement to manufacture drug substance for the Moderna COVID-19 vaccine.

Under the terms of the multi-year agreement, Resilience will produce mRNA for the Moderna COVID-19 vaccine at its facility in Mississauga, Ontario in Canada, for distribution worldwide.

"Moderna's COVID-19 vaccine has saved countless lives, and we're excited to manufacture mRNA for this important vaccine," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This collaboration has the potential to ensure more people are protected around the world from the deadly COVID-19 virus."

Separately, Moderna recently announced a collaboration to bring mRNA manufacturing to Canada through a Memorandum of Understanding (MoU) with the government of Canada to build a state-of-the-art messenger RNA (mRNA) vaccine manufacturing facility in the country including access to Moderna's mRNA development engine. The goals of this MoU are to build the foundation to support Canada with direct access to rapid pandemic response capabilities and to provide access to Moderna's vaccines in development for respiratory viruses.

About Resilience

Resilience is a manufacturing and technology company dedicated to broadening access to complex medicines and protecting biopharmaceutical supply chains against disruption. Founded in 2020, the company is building a sustainable network of high-tech, end-to-end manufacturing solutions with the aim to ensure the medicines of today and tomorrow can be made quickly, safely, and at scale. Resilience seeks to offer the highest quality and regulatory capabilities, and flexible and adaptive facilities to serve partners of all sizes. By continuously advancing the science of biopharmaceutical manufacturing and development, Resilience aims to free partners to focus on the discoveries that improve patients' lives.

National Resilience's $110 Million Alliance with Bluebird Bio to Develop Cell Therapies



October 14, 2021 Laura Testa

Tagged: Amanda Austin Georgina Jones Suzuki Katherine Hyland Marc Rubenstein Meredith Sterritt Michael Connolly National Resilience Rajarshi Banerjee Ropes & Gray Thomas Wechsler Zachary Cookston

Ropes & Gray advised National Resilience on the deal.National Resilience, Inc., a biopharmaceutical manufacturing specialist, closed a strategic alliance with bluebird bio, Inc., to accelerate the...

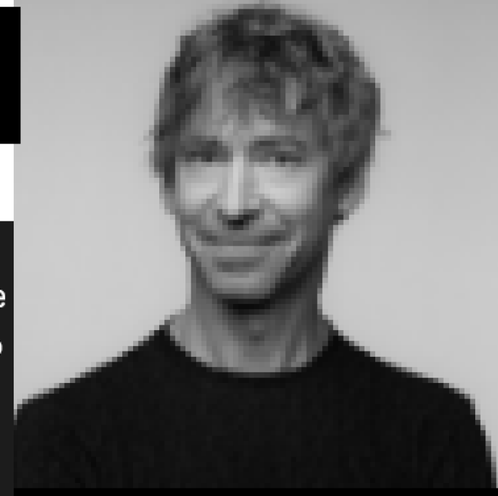
Luciana Borio



rn Rio de Janeiro, Brazil

iqt IN-Q-TEL

RESILIENCE



obert Nelsen

hairman and Founder, ARCH

However, while Nelsen has been given much of the credit for creating Resilience, he revealed in one interview that the idea for the company had actually come from someone else – Luciana Borio. In July of last year, Nelsen revealed that it was while talking to Borio about "her work running pandemic preparedness on the NSC [National Security Council]" that had "helped lead to the launch of Nelsen's $800 million biologics manufacturing startup Resilience."

At the time of their conversation, Borio was the vice president of In-Q-tel, the venture capital arm of the CIA that has been used since its creation in the early 2000s to found a number of companies, many of which act as Agency fronts. Prior to In-Q-Tel, she served as director for medical and biodefense preparedness at the National Security Council during the Trump administration and had previously been the acting chief scientist at the FDA from 2015 to 2017.

BORIO: IN-Q-TEL

+

Robert Nelsen: Resilience

Ology Bioservices Wins Three Department of Defense Awards Totaling More Than $16 Million

July 07, 2020 11:30 AM Eastern Daylight Time

Definitive Contract PIID W911QY20C0101

Includes COVID-19 Spending

Awarding Agency

Department of Defense (DOD)

Recipient

OLOGY BIOSERVICES, INC

13200 NW NANO COURT
ALACHUA, FL 32615-8726
Congressional District: FL-03
UNITED STATES

IndustrialBaseExpansion X

Ology Bioservices, Inc. USA

Product Name: Reservation of SARS-COV-2 Fill and Finish Manufacturing Capacity

Award Description:
This action will reserve production capacity for a total of approximately 15.57 M vials to satisfy an urgent need for reserve domestic aseptic fill / finish manufacturing capacity for critical vaccines and therapeutics that are being developed in response to COVID-19. It will help ensure an uninterrupted supply throughout the COVID-19 campaign.

Base Award Amount: $106,300,002.00 (August 17, 2020)

https://www.businesswire.com › news › home › 20171002005452 › en › Nanotherapeutics-Anno...

Nanotherapeutics Announces Name Change to Ology Bioservices, R...

The Company provides expertise from preclinical through FDA licensure in a variety of production platforms, including microbial and mammalian cell culture and its proprietary serum protein-free...

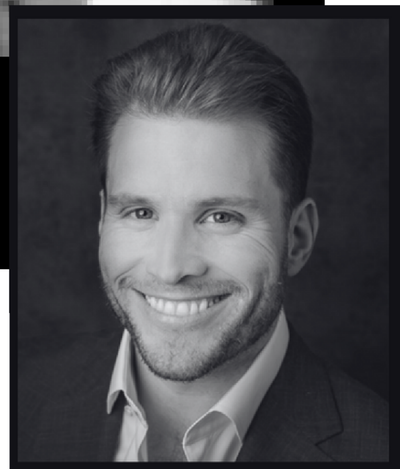
Borio is hardly Resilience's only In-Q-Tel connection, as the CEO of In-Q-Tel, Chris Darby, sits on the company's board of directors. Darby is also on the board of directors of the CIA Officers Memorial Foundation. Darby was also recently a member of the National Security Commission on Artificial Intelligence (NSCAI), where members of the military,



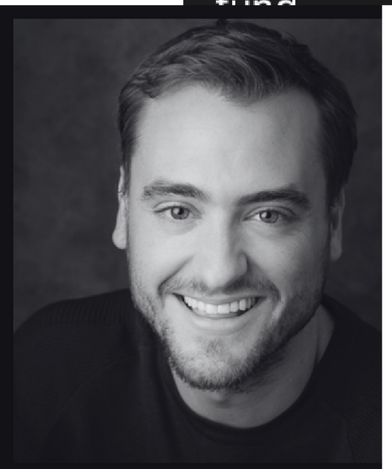
Chris Darby
CEO, In-Q-Tel

RESILIENCE

Oetting is also the co-founder of 8VC, a venture capital firm that is one of the main investors in Resilience. 8VC's other co-founder is Joe Lonsdale and Oetting "started his career" as Lonsdale's chief of staff. Lonsdale is the co-founder, alongside Peter Thiel and Alex Karp, of Palantir, a CIA front company and intelligence contractor that is the successor to DARPA's controversial Total Information Awareness (TIA) mass surveillance and data-mining program. In addition, Oetting previously worked for Bill Gates' investment fund



Joe Lonsdale



Drew Oetting

Another notable board member, in discussing Resilience's intelligence ties, is Drew Oetting. Oetting works for Cerberus Capital Management, the firm headed by Steve Feinberg who previously led the President's Intelligence Advisory Board under the Trump administration. Cerberus is notably the parent company of DynCorp, a controversial US national security contractor tied to numerous scandals, including scandals related to sex trafficking in conflict zones. Oetting is also part of the CIA-linked Thorn NGO ostensibly focused on tackling child trafficking that was the subject of a previous *Unlimited*

Palantir

Palantir

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RESILIENCE



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President, Purdue University,
Former Governor of Indiana



Chris Darby

CEO, In-Q-Tel

Resilience Articles in black all originial works by Whitney Webb



INVESTIGATIVE REPORTS

RNA for Moderna's Omicron Booster Manufactured by CIA-Linked Company

Since late last year, messenger RNA for Moderna's COVID-19 vaccines, including its recently reformulated Omicron booster, has been exclusively manufactured by a little known company with significant ties to US intelligence.

BY WHITNEY WEBB · AUGUST 17, 2022 · 31 COMMENTS



Author

Whitney Webb

Whitney Webb has been a professional writer, researcher and journalist since 2016. She has written for several websites and, from 2017 to 2020, was a staff writer and senior investigative reporter for Mint Press News. She currently writes for The Last American Vagabond and Unlimited Hangout

THE Sun



EXCLUSIVE

'BIGGEST COVER-UP IN HISTORY' I worked with the Wuhan lab – I tried to warn them & I KNOW Covid was a lab leak

News

Inovio Pharmaceuticals partners with Ology Bioservices on COVID-19 DNA vaccine

“We are sincerely optimistic about the partnership between Inovio and Ology Bioservices, in order to make doses of a vaccine that could potentially protect our military personnel. It is urgently needed,” Matthew Hepburn, joint project lead for CBRN Defense Enabling Biotechnologies, said.

JPEO-CBRND
Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense

10 USC 2373 AGREEMENT

BETWEEN

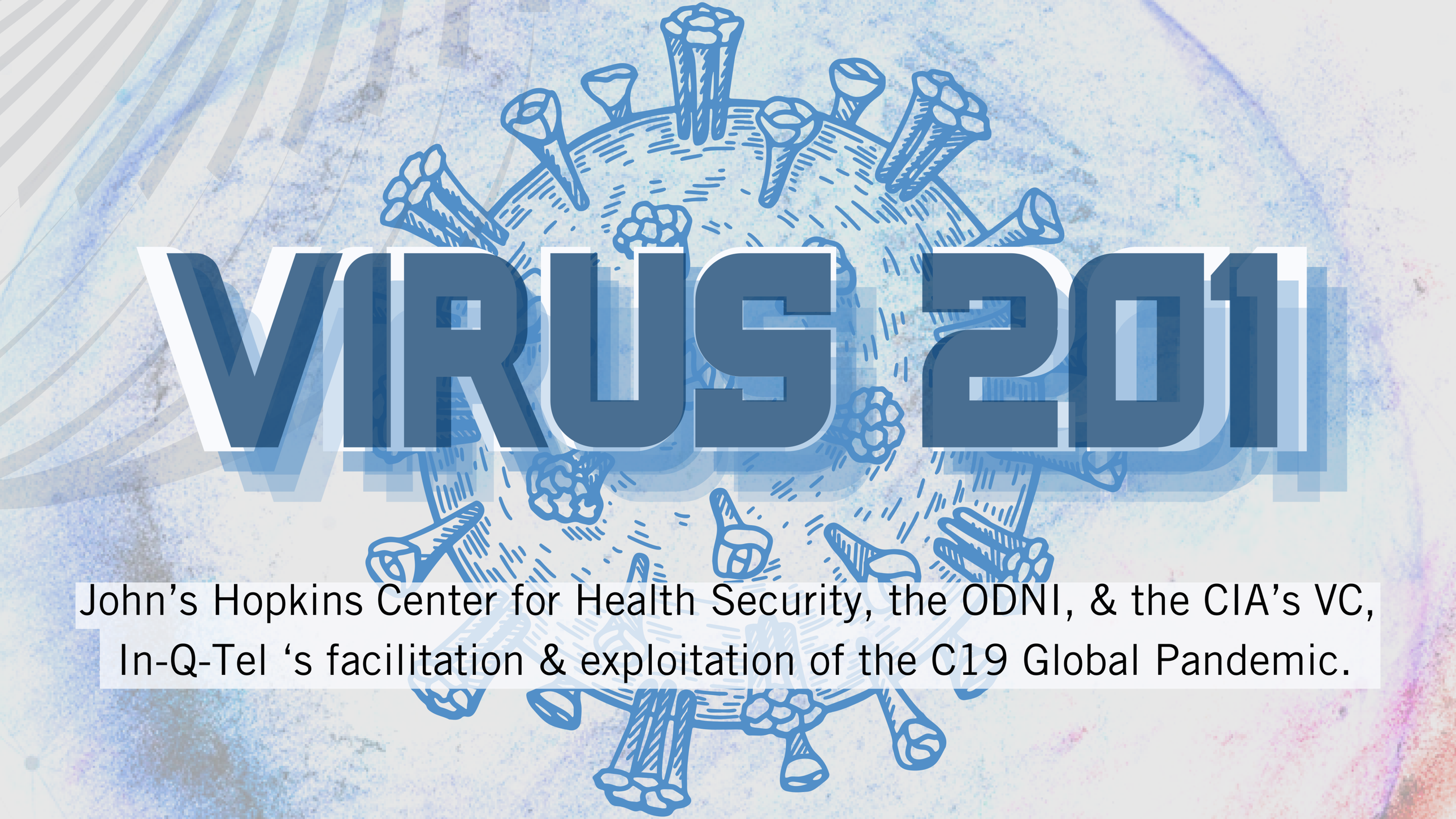
Ology Bioservices, Inc. (Awardee or Contractor)
13200 NW Nano Court
Alachua, FL 32615
And
NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date: 21 Feb 2020

Agreement No.: W911QY-20-9-0003

Total Amount of the Agreement: (b) (4)

Ology Bioservices, Inc.	**Government** (b) (6)
(b) (6)	
Signature	**Signature**
(b) (6)	(b) (6)
Printed Name	**Printed Name**
(b) (6)	Agreements Officer
Title	**Title**
21 February 2020	21 Feb 2020
Date	**Date**



John’s Hopkins Center for Health Security, the ODNI, & the CIA’s VC, In-Q-Tel ‘s facilitation & exploitation of the C19 Global Pandemic.

Delivering the biorevolution: a BNext Workshop on cellular delivery technologies

November 5, 2019

Dylan George[1], Tara O'Toole[2], BNext et al

Summary: This workshop was motivated by BNext's interest in technologies that facilitate timely response to infectious disease outbreaks through the rapid design and manufacture of vaccines against newly emergent pathogens.

A compelling technology for rapid response to an ongoing outbreak is nucleic acid-based vaccines. Nucleic acid-based vaccines are attractive for rapid response because, in theory, DNA or RNA antigens that provoke a protective immune response could be quickly and inexpensively designed, manufactured, and used speedily in the clinic. Big pharma and biotech companies are interested in advancing nucleic acid-based vaccines. Several candidates are in clinical trials, though no nucleic acid-based vaccines have achieved FDA approval. Among the hurdles associated with DNA or RNA-based vaccines are the following:

All Available Cellular Delivery Technologies Have Limitations - Major techniques to deliver the nucleic acid "payload" inside cells have been demonstrated - including electroporation, viral vectors and a variety of lipid nanocarriers – but all are problematic. Electroporation is suitable only for laboratory settings and not feasible in a mass casualty setting. Viral vectors carry the risk of unintentional immune reactions, and the virus carrier can only deliver certain types of payloads. Lipid nanocarriers are arguably the most advanced modality and are the delivery vehicle used in seven of eight ongoing RNA vaccine trials and in gene therapy trials. But they too are disadvantaged by the relatively "fragile" supply chain that is being used primarily for other products.

Manufacturing viruses and lipids is itself a hurdle to be overcome, especially if vaccine were needed in large quantities. For example, the supply chain capacity for GMP-grade lipids is limited, and currently being stretched by demand for the second-generation Shingles vaccine.

Similarly, manufacture of GMP-grade nucleic acid at scale is not currently possible at speed and would probably require 12 months. Making DNA in the U.S. Government's Advanced Development Manufacturing Facilities may make this possible in 6 months. Several biotech companies are working hard to improve de novo DNA synthesis, but we are not yet able to do this at the required scale and time frame. DARPA is starting a program to develop novel approaches for DNA manufacturing at scale too.

Regulatory approval of novel cellular delivery methods requires a time-consuming and costly investment of resources, a fact that creates a rational disincentive to innovate. Nonetheless, successful and safe cellular delivery is a central feature of many of the most promising new drugs, including gene therapies. The commercial stakes involved in these new approaches will likely advance the science of cellular delivery, hopefully to the benefit of nucleic acid-based vaccines.

Conclusions: Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers - should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

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[1] Vice President, BNext, IQT

[2] Executive Vice President, BNext Director, IQT

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technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

Manufacturing at scale: Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers[8] with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.

Background: Advances in synthetic biology are driving the creation of innovative therapies and vaccines that could transform rapid response capabilities for pandemics. These technologies – gene therapies, cell therapies, oncological immunotherapies, nucleic acid vaccines - require delivery of modified RNA or DNA to targeted cells to program those cells in order to have the desired clinical effect has significant technical challenges. On August 21, 2019, BNext convened a workshop of subject matter experts from industry, academia, and U.S. government agencies (Amy Jenkins – Program Manager DARPA, Mark Feinberg – CEO IAVI, Keith Wells – biomanufacturing consultant) to explore potential approaches to successful intracellular delivery technologies for vaccines which could be rapidly designed and quickly manufactured at a large scale. This paper reports on the workshop findings. The workshop was convened by B.Next, a division of IQT Labs, the research venture of In-Q-Tel (IQT).

Vaccines are critical tools for countering infectious disease outbreaks: Outbreaks of infectious diseases are an increasingly common, devastating feature of modern-day life which threaten lives and livelihoods. Modern patterns of trade, travel, commercial development drive such outbreaks. These outbreaks are fought by brave front-line clinicians and public health professionals armed with outdated data technologies, insufficient resources, and typically without effective vaccines or drugs. More often than not they fight outbreaks with 20th century tools. We need 21st century solutions to confront these 21st century health security challenges. At IQT we are actively pursuing technologies that provide the capabilities needed to respond to novel emerging infectious disease outbreaks.

Vaccines are the single most effective medical capability for countering infectious diseases (1), but vaccine development typically requires 15-20 years and approximately a billion dollars (2). The current process and enabling tools to discover, design, manufacture, and test a new vaccine are not well suited for rapid response. As a result of this long, expensive development process, vaccines historically have been unavailable to counter outbreaks of newly emergent disease (e.g., SARS 2003; Ebola 2014; Zika 2016).

One workshop participant told the group about how the lack of a deployable vaccine allowed the Ebola outbreak of 2014-2016 in West Africa to rampage across Sierra Leone, Liberia and Guinea killing over 11,000 people and significantly destabilizing the region. At the time, no licensed vaccine or therapeutic was available, but several candidate Ebola vaccines had already gone through years of early stage development. Merck Vaccines was willing and able to step into the breach to advance a candidate through later stage development. With support from the USG and others, Merck, at considerable expense, licensed a candidate vaccine, contracted manufacturing capabilities, and began the process of testing the vaccine in hopes of providing life-saving vaccines to people in the region. Merck was able to shorten the development timeline from years to months. Fortunately the outbreak ended before this vaccine could be manufactured and deployed at scale. So, in the end, the vaccine did not significantly contribute to stopping that specific outbreak.

Despite the example of Merck Vaccines and other initiatives[3], participants agreed that we continue to battle novel pathogen outbreaks without effective vaccines (3). Because time is critical during an outbreak, current methods of developing vaccines are not sufficient and technologies that can be designed and manufactured quickly will have more impact. Technologies that enable the discovery, manufacture, development, and use of vaccines in timeframes that would significantly counter an ongoing outbreak remain critically important. Promoting and developing vaccine technologies that enable rapid design and scaled-up manufacture has been a focus of some DARPA programs (e.g., Adept, P3). B.Next also continues to seek technologies that would enable vaccine design and manufacture in timeframes that would be applicable to stopping an epidemic.

Nucleic acid-based vaccines are promising technologies: Nucleic acid vaccines, which deliver DNA or mRNA to generate an antigen, are particularly promising vaccine technologies for rapid outbreak response because, at least in principle, they can be rapidly developed and inexpensively manufactured (4).

mRNA is the intermediate molecule that enables the expression of a gene into a protein. It is the molecule that tells a cell what proteins to build. The idea behind mRNA vaccines is to design and use an mRNA that would tell the body's cells to generate a particular type of protein, an antigen, that will elicit a protective immune response for a specific disease (Figure 1). In short, nucleic acid vaccines biologically "program" a person at the cellular level to generate immunological protection. This programming should work as long as you are able to deliver the right information, that is the right mRNA, to the right cells in a body.

[3] See efforts by the Coalition for Epidemic Preparedness Innovation, https://cepi.net/

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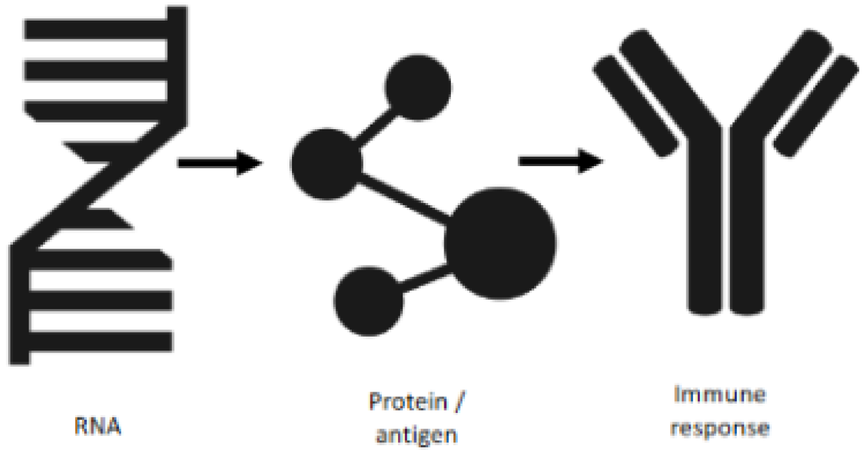


Figure 1. mRNA vaccines program cells to generate immune responses. mRNA vaccines accomplish immune responses by inserting an RNA molecule into cells to program the cellular production of a protective response in the body. The RNA molecule once in the cell is translated to a protein molecule. The protein, or rather antigen, elicits an immune response – generates antibodies or other mechanisms - that provides protection from the pathogen.

An advantage to mRNA vaccines is that RNA can be designed and, in theory, synthesized quickly using standardized processes. Traditional vaccine manufacturing is bespoke and typically requires a unique and expensive manufacturing facility for each vaccine, whereas with RNA production one manufacturing facility could be used for multiple vaccines because you are using a standardized system for RNA synthesis. Also, RNA-based vaccines can be manufactured cell-free, which reduces complications associated with maintaining GMP cell lines (5). Development of a mRNA vaccine can go from genetic sequence to mass production in three months, whereas traditional approaches would take many months to years to produce a new vaccine at scale. Despite such promise, however, no nucleic acid vaccines have yet been approved by the FDA, although several candidate vaccines have progressed to phase 1, 2 clinical trials (6).

Several participants were cautiously hopeful that mRNA vaccines could provide capabilities to address the challenges of rapid vaccine development, but the clinical trials still need to demonstrate candidate mRNA vaccines are safe and

Intracellular delivery: a vital component for effective vaccines: A major challenge with nucleic acid vaccines is getting the genetic payload to the right place in the body so one's immune system can generate protection. The safe and effective delivery of genetic payloads within humans has been a focus for decades (7), (8).

Intracellular delivery includes not just the process of getting materials through cellular membranes, but also entails protecting payloads from degradation processes, and releasing payloads into a cell in a reliable way (3). Intracellular delivery is a linchpin for a range of therapeutic applications beyond vaccines, including gene-editing technologies. Participants noted that several Phase I trials of nucleic acid vaccines nusing novel delivery technologies are underway (4), (8), (9).

Participants discussed the three main delivery modalities for vaccines: electroporation, viral vectors, and lipid nanocarriers.

Electroporation is the process of applying an electrical field to a cell such that cellular membranes become transiently permeable, molecular cargo moves across the membrane, the cargo can be inserted into the cell, and the membrane is resealed (Figure 2). Electroporation has been used in microbiology since the 1970s and is widely used in basic and biomedical research. But there are limitations to its use outside a lab or in a mass administration situation. The process can be highly efficient, but it is expensive and can create cell death if the electrical fields cause a permanent destabilization of a cell membrane or components. Electroporation can cause pain and muscle contractions which makes it less than appealing for treatment adherence if more than one dose is required. Most importantly, electroporation requires equipment to establish the electrical field and the portability of this equipment limits how widely it could be used outside of a clinic or laboratory setting. The value of electroporation is most apparent for *in vitro* and *ex vivo* investigations and applications, and not necessarily *in vivo* delivery.

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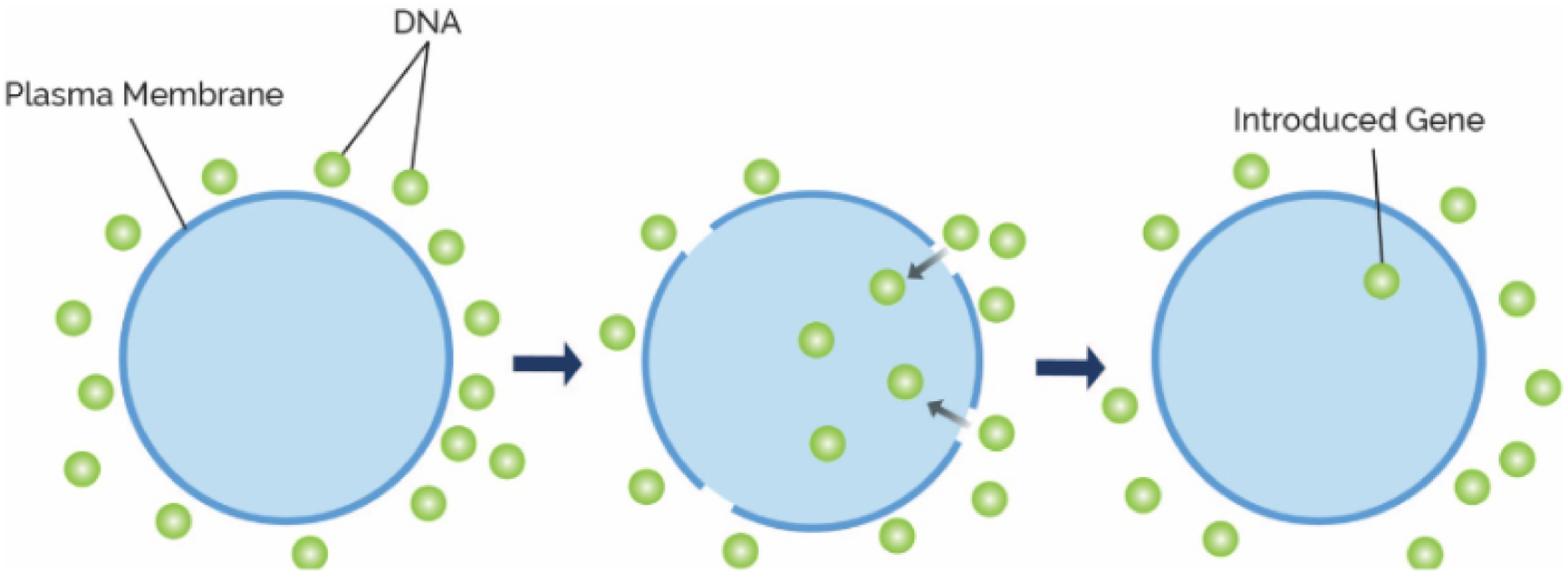


Figure 2. Electroporation is the process of applying a temporary electrical field to a cell. The electrical pulse causes transient pores to develop in the cell membrane. Material can be inserted into cells while pores remain open. [4]

Viral vectors are another intracellular delivery modality for therapeutics and vaccines. Viruses have been honed over evolutionary time to infect cells with genetic payloads. Simplistically, one can think of viruses as molecular machines with two functional components – the container and the cargo. Viral vectors use the natural infection machinery – the container - of a virus but with modified genetic material – the cargo - that is to be inserted into a target cell (Figure 3). Viral vectors have been used for decades and in many clinical trials (10), and have been used in gene therapies approved by the FDA[5]. Notably the recent recombinant vesicular stomatitis virus Ebola vaccine (11) and recent high profile gene therapies (12) use this approach.

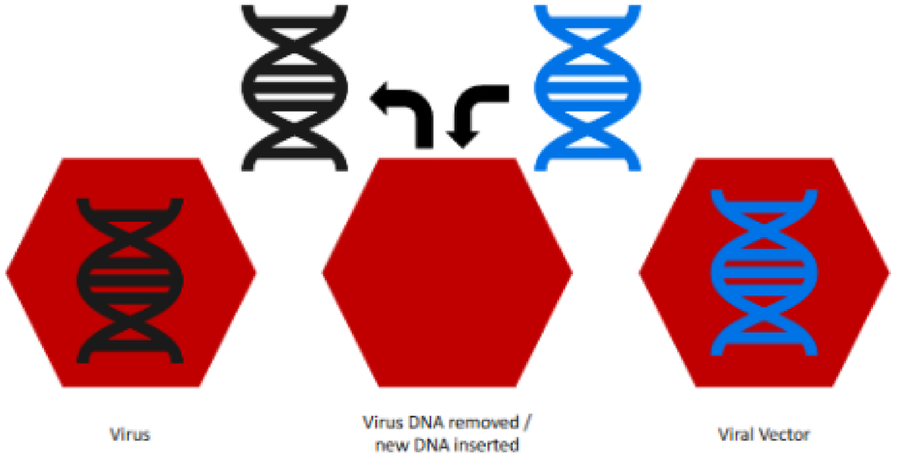


Figure 3. Viral vectors are made by using existing viruses, removing the virus DNA, and inserting new DNA that is to be used to program a cell for research or biomedical purposes.

However, this technology has limitations. The most well-known shortcoming of viral vectors has been unintentional immune reactions in patients. In 1999, a teenager suffering from a rare genetic disorder tragically died from an immune reaction to a viral vector used during a gene therapy trial. This tragedy set back the field of gene therapy for a decade. Even if we are able to avoid similar acute tragedies in the future, some people will produce

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[4] Based on a figure from https://courses.lumenlearning.com/microbiology/chapter/microbes-and-the-tools-of-genetic-engineering/

[5] Zolegensma is a gene therapy for treating pediatric patients with spinal muscular atrophy, and was recently approved by the FDA in May 2019. Zolgensma uses an adeno-associated virus vector for intracellular delivery of the gene therapy.

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immune responses to particular viral vectors. If this happens then the continued use of those vectors will not be possible in those individuals which will limit the therapeutics and vaccines that are in those vectors. Viral vectors are also limited by challenges in manufacturing large quantities of virus, the size of payloads, and by their ability to target many cell types. If the viral vector cannot infect certain types of cells, then we will not be able to program those cells with the genetic payloads. Finding viral vectors that can target specific cells will be an ongoing effort. So, researchers are actively searching for alternative viral vector systems to counter these limitations[6].

Lipid Nanocarriers - Delivering nucleic acids or proteins cargo into cells can be achieved by using chemical reagents to construct delivery vehicles that have different properties. Many alternative cell delivery approaches such as lipid nanocarriers, polymer nanocarriers, and other nanomaterials have been explored to bypass the limitations of viral vectors (13). Lipid nanocarriers are the most advanced of these technologies for nucleic acid delivery (8), are currently being used in the majority of current clinical trials on mRNA vaccines (6), and were used in the first RNAi drug ("Patisiran"), approved by the FDA in August 2018. A recent review of mRNA clinical trials and delivery modalities found that seven of the eight of the ongoing clinical trials on mRNA vaccines are using lipid nanoparticles as their intracellular delivery modality (6).

Carrier systems based on chemical reagents can be limited by the features of the cargo (e.g., size, chemical properties, unpackaging abilities) and the target cell types. As with viral vectors, getting into some cell types is easier than others depending on cell receptors, surface interactions, and internal cellular processing pathways. For example, immortalized cell lines can be easily transfected, whereas blood and neurological cells pose difficulties (8). Because lipid nanocarriers have been easier to make relative to viral vectors, generate adjuvant effects, and do not generate unintended immunogenic responses, they have been broadly used to deliver nucleic acids in drug development. But see below for the challenges associated with "fragile" supply chains associated with lipid nanocarriers.

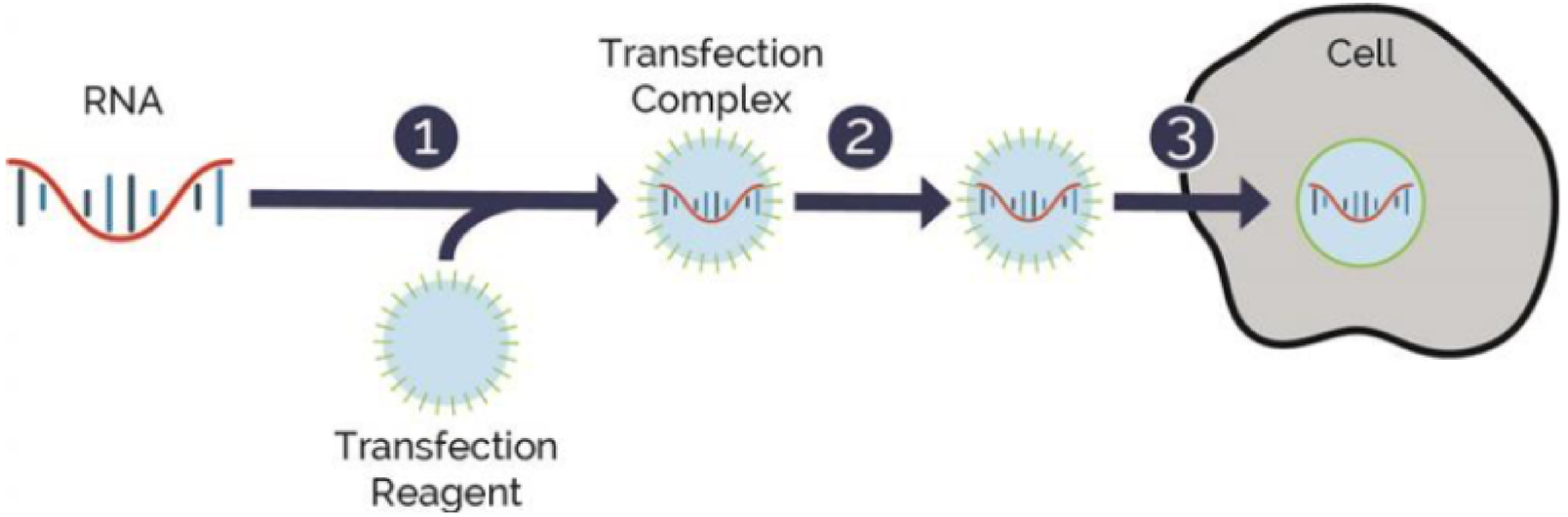


Figure 4: Getting programmed RNA into cells – the transfection process: **1)** A chemical reagent is combined with a nucleic acid making a chemical complex of the two entities. **2)** The combined reagent and nucleic acid interact with the cell surface. **3)** Cells internalize the complex and the nucleic acid is ultimately released to the cell cytoplasm. [7]

Challenges and opportunities:

Regulatory: A major regulatory issue is the innovation disincentive within big pharma. An effective regulatory environment for medical countermeasures is necessary but can slow innovation. For biological pharmaceuticals such as vaccines, the manufacturing process itself contains much of the valuable intellectual property. To meet regulatory standards, the production process must reliably produce the same product which requires considerable investment of time and resources. Once a process has been validated and approved by a regulatory agency there is a rational disincentive to modify the process because major changes would require further regulatory approval and cost to provide the needed data. (14). Regulatory disincentives slow the pace of innovation for intracellular delivery

[6] For example, see the company Ring Therapeutics.
[7] Based on figure from https://www.mirusbio.com.

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technologies. Viral vectors and lipid nanocarriers are the delivery modalities that are furthest along in clinical trials for gene therapies (8) and mRNA vaccines (6); however, alternative delivery technologies – commensal viral vectors, polymer nanocarriers – need to be supported and tested as well.

Manufacturing at scale: Even when a vaccine that has been designed and tested in animal studies is available, manufacturing it at scale is challenging, especially for an ongoing outbreak that requires vaccine to be delivered quickly. Biotechnology companies typically lack resources to push vaccine development beyond preclinical work and early clinical trials. Late stage clinical trials and constructing unique manufacturing facilities drive the high costs associated with vaccine development. There are few major manufacturers[8] with the needed expertise working on vaccines (2), and they traditionally have developed bespoke manufacturing capabilities which constrain the speed and ability to pivot to novel threats.

The limits of current manufacturing have been a major motivation for developing nucleic acid vaccines which can be developed and produced at scale much more quickly than traditional approaches. One participant noted that while nucleic acid vaccines are promising, manufacturing quality nucleic acids at the scale needed for a mass outbreak have not been completely figured out (9) and likely will be deficient because manufacturing clinical GMP DNA can take anywhere from six to twelve months. Also, a participant highlighted that gene and cell therapies using delivery technologies will not require the same scale of manufacturing as would mRNA vaccines especially during surges of an ongoing outbreak. So, relying on commercial markets to develop the needed capacity may not yield the quantity of material demanded by a pandemic scenario. New synthetic biology approaches to manufacture DNA enzymatically instead of chemically potentially could be a means of addressing the manufacturing shortfall of clinical GMP DNA. Exploration of the potentials and deficiencies in nucleic acid synthesis are needed. Companies developing enzymatic approaches of DNA synthesis are exciting and warrant further attention as do companies developing novel, nimble, and efficient biomanufacturing capabilities.

Supply chain constraints: One participant reminded the group that as we think about new technologies for outbreak response, we need to think about manufacturing capability and the supply chain of constituent materials, particularly we need to consider "fragile" supply chains. Constraints in manufacturing supply chains may limit the development and use of nucleic acid vaccines and delivery technologies. Competing markets for component materials have caused shortages for manufacturing clinical GMP lipid products. A good example is the vaccine called Shingrix[9]. This vaccine prevents shingles (herpes zoster) and is made up of the antigen, glycoprotein E, and an adjuvant, AS01B. People generally lose capacity to generate an immune response as they age, and the vaccine was developed specifically to generate immune responses in older people. The adjuvant is critical to generating the immune response, and is liposome based. The market for Shingrix is large. So, GlaxoSmithKline, the manufacturer, has acquired a major portion of the lipid supply to maintain Shingrix production which has disrupted the lipid supply chain for other uses. It remains unclear if these lipid supply chain challenges will persist or manufacturing capabilities will eventually compensate. But, in the short run the lack of raw materials will delimit manufacturing capabilities for other lipid-based products such as delivery technologies.

Conclusions: The workshop found that there were persistent scientific, regulatory, manufacturing, and supply chain challenges for advancing nucleic acid vaccines and delivery technologies. Significant research is ongoing in novel delivery modalities and it will be exciting to see those results in the next few years. The interface of regulation and innovation will continue to provide safety assurances yet will disincentivize the adoption of innovation in biomanufacturing. Supply chains for component materials will be a fluid environment and should be monitored because they could significantly limit capacity during an outbreak scenario. Advances in delivery modalities other than the current mainstays – existing viral vectors, lipid nanocarriers - should be supported. Supporting alternative DNA synthesis technologies and nimble, efficient biomanufacturing capabilities should be a priority.

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[8] For example, GlaxoSmithKline, Merck, Pfizer, Sanofi Pasteur

[9] https://www.shingrix.com/index.html

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b.next IQT

ROUNDTABLE REPORT – LEVERAGING DIGITAL HEALTH TECHNOLOGIES DURING LARGE-SCALE EPIDEMICS

December 2019

Introduction

The capabilities required to manage a large-scale epidemic are multifaceted, complex and range across a number of critical domains – the ability to detect and recognize the presence of disease in the community; the capacity to design, manufacture and deliver life-saving medical countermeasures, including therapeutics and vaccine; and the process by which healthcare services can be delivered to the population-in-need in a scalable fashion that maintains the highest possible standard of care.

Background

In-Q-Tel/B.Next convened a Roundtable meeting, held on December 5, 2019 in Arlington, VA to explore the role digital health technologies can play to support the response to large infectious disease outbreaks. Roundtable participants included experts drawn from several United States (U.S.) Government agencies, academia, private-sector technology companies and members of the In-Q-Tel and B.Next team. The discussion took place over a single day. There were two invited presentations, and the meeting was conducted on a not-for-attribution basis.

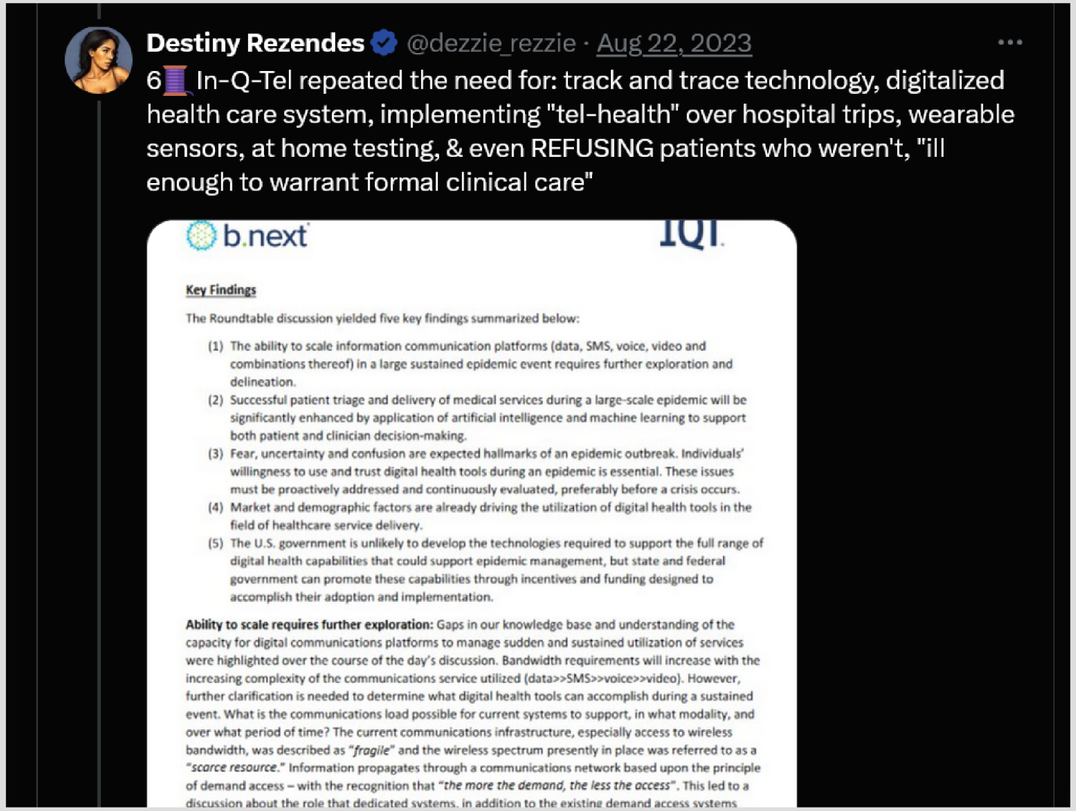
This Roundtable discussion was the first of a series of meetings which intend to explore how digital health technologies might be applied to epidemic management. This meeting was focused expressly on two broad themes -- the role enabling technologies can play in allowing the population to initiate self-triage, and how such technologies might aid in preserving the integrity of hospital services over the course of an extended outbreak event. Subsequent Roundtable discussions in this series will explore the potential of these technological platforms to help provide appropriate medical treatment in an austere environment where resources are scarce. We will also examine how digital health technologies might enable the collection, analysis and coordination of data in order to provide essential situational awareness, thereby facilitating the creation of a "learning healthcare system" in the midst of an epidemic crisis.

Overview of Topic: *Digital Health tools will be critical to managing epidemic events.*

The potential roles that digital health technologies might serve during an epidemic requires an understanding of the likely adoption rate, capabilities, and limitations of such technologies. The rationale for this approach is based upon three key points. The first is that healthcare service delivery is currently undergoing a fundamental shift toward the increasing adoption of digital health tools. Changes in the marketplace are driving rapid changes in healthcare service delivery. These forces include the need to reduce costs and respond to patient demands for more efficient access to care. The second is that the platforms that support digital health tools – namely the adoption of the smartphone with its consumer facing applications, along with the extension of broadband internet connectivity – are widely available in the U.S. This facilitates the ability to exchange meaningful and timely health-related

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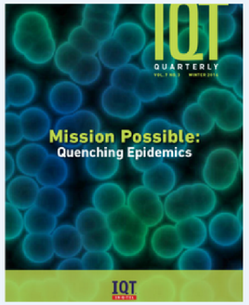


WINTER 2017



Building an Effective Defense against Biological Threats: the Technology Advantage

WINTER 2016



Mission Possible: Quenching Epidemics

FALL 2016



3D Imaging

SUMMER 2016



The Inevitable Internet of Things

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SPRING 2019



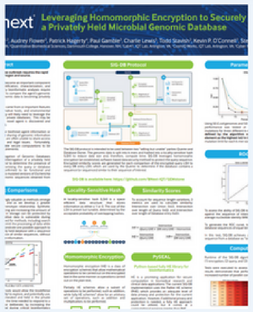
Understanding Artificial Intelligence Applications in Bioscience and Biotechnology

FALL 2018



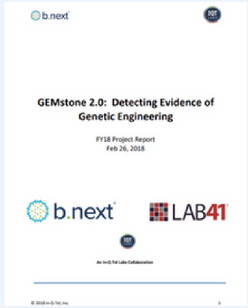
GEMstone 2.0: Secure Interrogation of Genomic Databases

FALL 2018



Secure Interrogation of Genomic Databases — ASM Biothreats 2018

SUMMER 2018



GEMstone 2.0: Detecting Evidence of Genetic Engineering

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WINTER 2023



Roundtable Report: Identifying, Collecting and Analyzing Actionable

WINTER 2019



Digital Health Roundtable

FALL 2019



Drug Delivery Workshop

FALL 2019



Testimony of Tara O'Toole, MD, MPH

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Munich Re & In-Q-Tel Select Metabiota to Gain Deeper Insights into Epidemic Risk and Global Preparedness for Infectious Diseases

AUG. 22, 2017

Building an Effective Defense Against Biological Threats: The Technology Advantage

MARCH 20, 2017

The United States faces significant and growing national security threats from increasingly frequent and disruptive natural epidemics of infectious disease and potentially from covert biological weapons attacks on civilian populations. To address this issue, "Building an Effective Defense Against Biological Threats: The Technology Advantage" discusses how strategic adoption of existing and emerging biotechnologies, and use of digital communications and analytical tools, could greatly improve epidemic detection and management. The piece is written by IQT Executive Vice President Tara O'Toole, M.D., MPH.

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iqt B.NEXT

IQT Roundtable: Capabilities Required for Pandemic Response – August 2021

Introduction

On August 12, 2021, In-Q-Tel (IQT) convened a virtual Roundtable meeting to examine the technologies used to respond to the Covid-19 pandemic and other epidemics, to discuss what needed capabilities were missing from the Covid response, and how these critical needs might be addressed. Roundtable participants included experts drawn from several United States government (USG) agencies, academia, private-sector technology companies, and members of the IQT/B.Next team [see Roundtable Participants pg. 14]. The meeting was conducted on a not-for-attribution basis.

For over two decades, increasingly frequent and consequential outbreaks of infectious disease have demonstrated that we are living in an "age of epidemics". It is urgent that nations become more adept, individually and collectively, at controlling disease outbreaks. While improving global preparedness requires changes in national, institutional, and individual behaviors, many of the capabilities required to respond to lethal, fast-moving epidemics are technologies which can be realized through collaboration among governments, universities and private companies.

Our collective struggle against Covid-19 has demonstrated that technologies, ranging from diagnostic tests and vaccines to personal protective equipment and contact tracing apps, are essential to the task of quenching pandemics. Yet, with a few exceptions, analyses of how technologies might enable critical pandemic management functions, and the strategies required to make such technologies widely available for this—or the next—pandemic, remain the exception, not the rule.

Public policy / engagement goals:

- Communicate advances in support of the above goals to the public on an ongoing basis to establish credibility between outbreaks
- Engage communities with proven expertise (such as Silicon Valley) to improve best practices in getting the public to adopt new technologies
- Recognize that behavioral and cultural changes, along with vaccines, are a line of defense ahead of protective equipment

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Effective Response to Future Pandemics Requires Imagination and Aggressive Efforts Now

The COVID-19 pandemic has served as a "forcing function", driving adoption of innovative technologies such as telemedicine, smart phone diagnostic applications, and the first large scale manufacture and use of mRNA vaccine technologies. But these technologies mostly existed before the pandemic and their use during Covid, though vital, represented incremental technological progress rather than radical improvements.

The Covid-19 pandemic did not, for example, catalyze the use of technologies such as microneedle patches, sublingual delivery systems, etc. that might have allowed self-administration of vaccines without needles or syringes. Such delivery technologies might have increased vaccine uptake and relieved some of the burden on medical and public health systems. These technologies already exist commercially, but the small companies producing them found it challenging to gain attention or scale up during the crisis.

The design, testing and manufacture of effective mRNA vaccines within one year of the virus being sequenced by Operation Warp Speed "set a new normal" and demonstrated the importance of putting multiple efforts and solutions into play simultaneously. Such a strategic approach to innovation demands significant resources on a scale only governments can muster. The expertise and willingness to make difficult decisions, prioritize what is important, and remove bureaucratic restrictions are also essential. But only the private sector has the talent and capacity develop and manufacture medical countermeasures.

It remains unclear what will happen to the more than 100 Covid-19 vaccine candidates still completing clinical trials. Market forces alone are unlikely to promote novel vaccines beyond those which have already gained regulatory approval. Yet it is possible that some of these pipeline vaccines could prove essential in the next pandemic.

Still to be realized – or even imagined in detail – is the essential goal of making and distributing enough vaccine for the world's population. In the present era of global trade and travel, a national approach to pandemic control is doomed to failure. Clearly, an enormous increase in the Covid vaccine manufacturing capacity is needed. How to do this efficiently and in a manner that enables governments and industry to mount rapid responses to emergent pathogens in this age of epidemics is an urgent priority.

Effective detection, management and resolution of infectious disease epidemics requires a societal-wide response. The Covid-19 pandemic should provoke a critical review of the authorities, processes and resources that were brought to bear against this ferocious virus which has done so much damage. But we should also consider how we might make better use of technologies to save lives and halt disease transmission. If we remain reliant on conventional technological approaches, or allow market forces to set the pace of adopting new technologies, we will miss the opportunities to create the capabilities we need to respond rapidly to coming outbreaks – and to quench them before they become pandemics.

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Roundtable – Participants

JJ Ben-Joseph is a Data Scientist at IQT Labs who works in the confluence of biosecurity and artificial intelligence, advises startups, and contributes to technical projects. He has a computer science degree from Johns Hopkins and previously worked for the National Security Agency.

Nathan Bergin is the B.Next intern at IQT this summer, focusing on innovation systems and biodefense strategies. After IQT, he will join Deloitte Consulting as a Strategy Analyst in the Government and Public Services Practice. He holds a Bachelor of Science in Foreign Service from Georgetown University with a concentration in biotechnology and global health.

Jane Bigham, MPH is a Senior Health Policy Advisor for the Senate Committee on Health, Education, Labor, and Pensions Majority Staff (Senator Murray, D-WA). She previously worked at the Centers for Disease Control and Prevention and at the Carter Center. She holds an MPH from Emory University and a B.A. in Psychology and Spanish from Agnes Scott College.

Luciana Borio, MD is a senior fellow for global health at the Council on Foreign Relations (CFR) and a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. She previously held positions on the National Security Council and as a Vice President at IQT.

Joe Buccina is a Director of Intelligence Community Support and B.Next Operations. He focuses on customer engagement, team operations, and bioinformatics. Before joining the B.Next team, he was an IQT program manager, a public sector consultant, and a biosurveillance analyst at a startup.

Eugene Chiu is a Senior Partner on In-Q-Tel's Investments Team, leading IQT's investments in healthcare and life sciences ventures with IQT's B.Next team. He has also been responsible for a number of IQT investments in the areas of quantum computing, advanced analytics, and artificial intelligence. Prior to IQT, Eugene co-founded and led business development, marketing, and commercial operations at multiple venture-backed companies. Eugene earned his A.B. in Biochemical Sciences from Harvard College, Master's in Health Sciences and Technology from MIT, and MBA from Harvard Business School.

David H. Donabedian, Ph.D. is a Venture Partner at Longwood Fund, Startup CEO of Longwood-founded ImmuneID, and was the founding CEO of Longwood-founded Axial Therapeutics, a biotechnology company focused on the gut-brain axis. Prior to joining Longwood, Dr. Donabedian held various leadership roles at biopharmaceutical companies including AbbVie (NASDAQ: ABBV) and GlaxoSmithKline (NYSE: GSK). Dr. Donabedian holds a B.A. in Chemistry from St. Anselm College, a Ph.D. in Polymer Chemistry from the University of Massachusetts Lowell, and an MBA from the University of North Carolina.

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Asha M. George, DrPH (invited) is the Executive Director of the Bipartisan Commission on Biodefense. She served on the Biden-Harris Transition Team and as a subcommittee staff director and senior professional staff for the US House of Representatives Committee on Homeland Security. She is a public health and national security expert.

Dylan George, Ph.D. is a Vice President at Ginkgo Bioworks where he is helping to develop improved biosecurity, surveillance, analytics, and capabilities to better engineer organisms. Prior to Ginkgo, Dr. George was a Vice President at In-Q-Tel (IQT) and held various positions in the United States Federal government (DoD, HHS, OSTP) where he developed analytics, promoted authorities, coordinated budgets, and enabled policies for better pandemic response and preparedness capabilities.

Peter Haaland, Ph.D. is a freelance applied scientist and inventor solving transdisciplinary problems by way of IARPA, DARPA, the USAF, early-stage VC, and diverse advisory activities in government and industry.

Dan Hanfling, MD is a Vice President on the Technical Staff at In-Q-Tel and a practicing emergency physician with expertise in operational emergency medicine. Prior to coming to In-Q-Tel he spent four years at HHS/ASPR, and before that led healthcare emergency management efforts for the Inova Health System (Falls Church, VA). He currently co-chairs the National Academy of Medicine's Forum on Medical and Public Health Preparedness.

Matthew Hepburn, MD is the Director of COVID Vaccine Development for the HHS-DoD Countermeasures Acceleration Group (formerly known as Operation Warp Speed). Prior to this he served as the Joint Project Lead for Enabling Biotechnologies for the Joint Program Office for Chemical, Biological, Radiological and Nuclear Defense (DoD), was a Program Manager at DARPA (2013-2019), and served as the Director of Medical Preparedness on the White House National Security Staff (2010-2013).

Amy Jenkins, Ph.D. joined DARPA as a Program Manager in June 2019. Her interests include the development of platforms for combatting infectious disease threats as well as novel manufacturing methods to enable rapid response. Prior to joining DARPA as a PM, Dr. Jenkins was a Senior Scientist at Gryphon Schafer where she contributed to development of programs targeting infectious disease threats within BTO. Prior to supporting DARPA, Dr. Jenkins studied the virulence factors of, and antibodies targeting, multi-drug resistant bacterial pathogens at MedImmune. She also served as a National Research Council Postdoctoral Fellow at the United State Army Medical Research Institute of Infectious Diseases where she studied virulence mechanisms of biodefense pathogens. She received her Doctor of Philosophy degree in Chemistry and Chemical Biology from Cornell University and her Bachelor of Science in Chemistry and Biomolecular Science from Clarkson University.

Robert Kadlec, MD is the former Assistant Secretary for Preparedness and Response at the Department of Health and Human Services and a member of Senator Richard Burr's (R-NC) staff.

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He spent more than 20 years as a career officer and physician in the United States Air Force before retiring as a Colonel. Over the course of his career, he has held senior positions in the White House, the U.S. Senate, and the Department of Defense. He holds a bachelor's degree from the United States Air Force Academy, Doctorate of Medicine and Masters of Tropical Me and Hygiene from the Uniformed Services University of the Health Sciences, and Master's d in National Security Studies from Georgetown University.

Kathryn Kosuda, Ph.D. is co-founder and CSO at Vaxess Technologies, a life science company focused on improving the efficacy and accessibility of vaccines using MIMIX™, a novel stabilization and skin delivery platform. Kathryn holds a PhD in Physical Chemistry from Northwestern University, did her postdoctoral research in the Department of Chemistry & Chemical Biology at Harvard, and began her career in pharmaceutical R&D at Merck Research Laboratories.

James Lawler, MD, MPH is Executive Director for International Programs and Innovation for the Global Center for Health Security at at the University of Nebraska Medical Center. He is also an Associate Professor of Medicine in Infectious Disease and Deputy Medical Director for the Nebraska Biocontainment Unit. Before joining the UNMC team in November 2017, he served 21 years in the US Navy Medical Corps. Dr. Lawler's work has spanned a broad array of research, policy, and field activities related to emerging and high-consequence infectious diseases, medical and public health preparedness, pandemic and outbreak response, and global health. Dr. Lawler served in national policy positions in both the White House Homeland Security Council Biodefense Office and the National Security Council Resilience Directorate spanning two administrations.

James Lim is a Summer Investment Associate at In-Q-Tel, focusing on the biotechnology/healthcare and enterprise technology sectors. He is a fourth-year JD/MBA candidate at Harvard Business School and Harvard Law School, and holds a B.A. in Economics from Harvard College.

W.B. "Mitch" Mitchell currently serves as Group Vice President, Government Solutions with Amwell. Mitch is a senior strategy and management professional with over 25 years passionately building businesses in healthcare and information technology. He combines expertise in Military and Veteran's Health, Telemedicine, Federal Health Programs, Patient Engagement and Clinical eHealth Strategy Development. Before joining Amwell, Mitch led Government Solutions for Ciox Health and for 15 years prior, Mitch led teams across McKesson/RelayHealth and Change Healthcare, supporting complex commercial and federal health IT, HIE and patient engagement programs.

Kevin O'Connell, Ph.D. is Vice President and Technical Co-Lead for B.Next, the IQT technology practice focused on life sciences and the intersection of biotechnology, healthcare, and national security. Prior to joining IQT, he was a researcher and principal investigator with the U.S. Army Edgewood Chemical Biological Center for 10 years, where he focused on pathogen detection and genetic characterization. He holds a bachelor's degree in life sciences from MIT, and MS and PhD degrees in bacteriology from the University of Wisconsin-Madison.

Tara O'Toole, MD, MPH was Executive VP and Senior Fellow at IQT since 2014 and is now an IQT Sr. Fellow. She served as Under Secretary of Science and Technology at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from1993-97. She was a founding member and Director of the organization now known as the Johns Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

Sandeep Patel, Ph.D, is the Director of BARDA's Division of Research, Innovation, and Ventures (DRIVe). Prior to DRIVe, he founded KidneyX and PreventionX at the Department of Health and Human Services. He holds a Ph.D. from Georgia Tech and a B.S. from Washington University in St. Louis.

Martijn Rasser is a senior fellow and director of the Technology and National Security Program at the Center for a New American Security (CNAS). Prior to joining CNAS, he was an executive at an AI startup and a hedge fund. He is a former CIA officer.

Lewis Rubinson, MD, PhD is the Chief Medical Officer of Morristown Medical Center (MMC) within the Atlantic Health System (AHS). Dr. Rubinson is a critical care physician and the physician executive lead for the COVID-19 response at MMC, which was one of the early impacted referral hospitals. At the peak of the COVID-19 surge in the of Spring 2020, MMC had 20 COVID-19 inpatient units with more than 300 inpatients and more than 100 persons requiring mechanical ventilation. MMC has cared for nearly 3500 hospitalized persons with COVID-19 and AHS for nearly 8500 hospitalized patients. AHS has administered thousands of doses of monoclonal abs, hundreds of thousands of vaccination doses, enrolled 100s of patients in therapeutic trials and has implemented numerous testing platforms for COVID-19/ SARS-CoV-2.

Patrick Rose, Ph.D. is the Program Manager for the Department of Defense Bioindustrial Manufacturing Innovation Institute: BioMADE. In this role, he represents the government in a public-private partnership to address the spectrum of manufacturing challenges associated with biomanufacturing of non-medical products. He also serves as Science Director for Synthetic Biology at the U.S. Office of Naval Research Global in London, United Kingdom. In his position, Dr. Rose is responsible for maintaining a global network throughout the synthetic biology community and provides general technology awareness to the US Navy.

Sarah Sewall Ph.D. is the Executive Vice President for Policy at In-Q-Tel. From 2014-2017, she served as Under Secretary of State for Civilian Security, Democracy and Human Rights. During the Clinton Administration, she served as the inaugural Deputy Assistant Secretary of Defense for Peacekeeping. Dr. Sewall taught at Harvard for over a decade, where she directed the Carr Center for Human Rights Policy and worked closely with the U.S. military to advance civilian protection in war.

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Inder Singh is the founder and CEO of Kinsa. With a network of 2.5M households, 5% of US elementary schools, and numerous enterprises that use Kinsa's illness insights tools, Kinsa helps families, communities and the system predict, prepare for, and prevent the spread of infectious illness. Kinsa built its early warning system for spreading infectious illness from the bottoms up: by first re-imagining the thermometer into a two-way communication channel to the newly sick and leveraging it collect the "missing ingredient" data—for example, real-time symptom onset, and intra-family transmission rates—and delivering outbreak insights back to these families, school communities and enterprises. Prior to founding Kinsa, Inder served as the Executive Vice President of the Clinton Health Access Initiative. He holds 3 graduate degrees from Harvard and MIT and is a proud University of Michigan alum.

Alexander Titus Ph.D. is currently the Head of Public Sector Healthcare and Life Sciences Strategy at Google Cloud as well as an Adjunct Assistant Professor of Biotechnology at the University of New Hampshire and the founder of Bioeconomy.XYZ. Prior to Google, Titus was the head of biotechnology strategy at the Department of Defense, leading the team developing the modernization roadmap for the department. Titus is also a genomic data scientist by training with a PhD in Quantitative Biomedical Sciences from Dartmouth College and a BS and BA in biochemistry and biology (respectively) from the University of Puget Sound.

Raffaela Wakeman is the Director of Policy at In-Q-Tel. She previously served as Staff Director for the Strategic Technologies and Advanced Research Subcommittee of the House Permanent Select Committee on Intelligence and has experience at the Department of Defense, Department of Justice, Department of Treasury, and The Brookings Institution. She holds a JD from Georgetown University Law Center and an MS and BS in Political Science from MIT.

Chenny Zhang is an Associate on IQT's Investment Team. She previously worked as a Program Manager at In-Q-Tel, for the Defense Innovation Board, and as a Program Manager for Cisco. She holds an MA in International Economics and China Studies from Johns Hopkins University and a BA from Boston College.

John Zicker is Data Science Vice President at Kinsa. He was previously Chief Data Scientist and conDati, CEO at Amplion, COO at Vree Health, and has experience as a founder and leader of multiple start-ups. He holds a MSEE in Biomedical Engineering from the University of Wisconsin-Madison and a BSEE from the University of California-Davis.



Central Intelligence Agency

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Moderna and Pfizer/BioNTech vaccines to their respective fact sheets.[46][47]

In September 2021, the company began work on a combined COVID-19 vaccine booster and influenza vaccine.[53] That same month, it entered an agreement with biomanufacturing company National Resilience to manufacture genetic components for its COVID-19 products at its facility in Mississauga, Ontario.[54]

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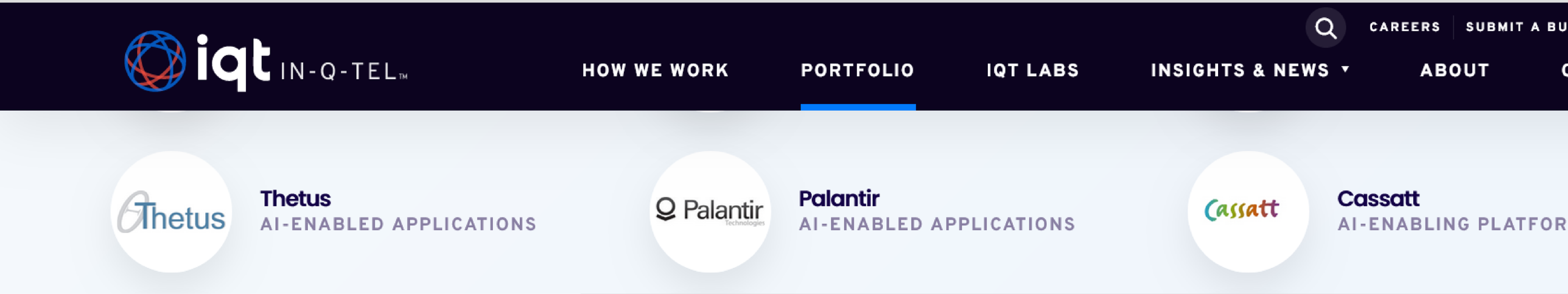
Luciana Borio: Former FDA Chief Scientist, VP of the CIA's In-Q-Tel, CFR, COVAX, President's Transition COVID-19 Advisory Board, Arch Ventures, Inspired the creation of Moderna's C19 Manufacturer, National Resilience Inc, Johns Hopkins Alumni & Advisor, Partner w. BMGF

Robert Nelson: Founder & Board of Directors for National Resilience [Moderna's C19 manufacturer], Founder of Arch Ventures, CFR

Chris Darby: Board of Directors for National Resilience [Moderna's C19 manufacturer], President of the CIA's In-Q-Tel.

Tara O'Toole: Senior Advisor at Johns Hopkins Center For Health Security [JHCHS], Pandemic exercise author: Crimson Contagion, Dark Winter, B.Next Lab, VP In-Q-Tel, Under Sec of Homeland Security for Science & Tech under Obama.

A**vril Haines**: Former CIA Director under Obama, Managing Director for President Biden's Transition Team, Event 201 Player, Johns Hopkins University Drop-out, current director for the ODNI, Georgetown Alum.



Palantir [Joe Lonsdale Nathan Wolfe]: Lonsdale co-founded Palantir which the USG hired for the Operation Warp speed platform “Operation Tiberius” that was in charge of the delivery & tracking of every US dose of C19 Vaccine. Nathan Wolfe founder of Metabiota & Palantir have collaborated together on multiple projects over the past 10yrs. Lonsdale is on the Board for Resilience.

Metabiota {Hunter Biden/Nathan Wolfe}: Worked w/ EcoHealth Alliance in the years preceding the pandemic. In-Q-Tel began financing them in 2017. Hunter Biden became a majority stock holder in Metabiota in 2014. In In-Q-Tels 2019 IRS-990 Metabiota was listed under the top 5 contracts with In-Q-Tel at over $1.3Million

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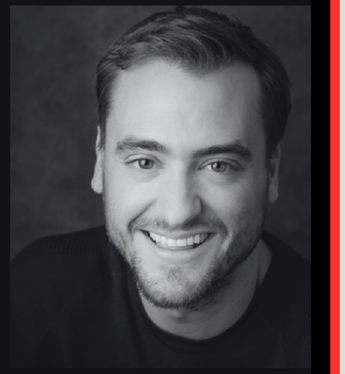
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Chairman and Founder, ARCH



Patrick Y. Yang, PhD
Vice Chairman, Former EVP Juno
Roche, Genentech



Joe Lonsdale



Drew Oetting



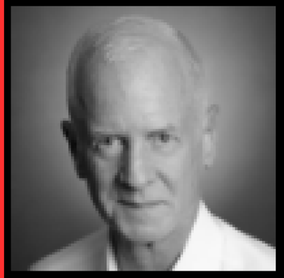
Frances Arnold, PhD
Nobel Prize Laureate, CalTech
Professor



George Barrett
Former Chairman & CEO,
Cardinal Health



Mitchell E. Daniels, Jr.
President, Purdue University,
Former Governor of Indiana



Chris Darby
CEO, In-Q-Tel

Oetting is also the co-founder of 8VC, a venture capital firm that is one of the main investors in Resilience. 8VC's other co-founder is Joe Lonsdale and Oetting "started his career" as Lonsdale's chief of staff. Lonsdale is the co-founder, alongside Peter Thiel and Alex Karp, of Palantir, a CIA front company and intelligence contractor that is the successor to DARPA's controversial Total Information Awareness (TIA) mass surveillance and data-mining program. In addition, Oetting previously worked for Bill Gates' investment

World Health Organization + WORLD BANK GROUP Health, Nutrition & Population

GPMB GLOBAL PREPAREDNESS MONITORING BOARD

The WHO + The World Bank created the Global Preparedness Monitoring Board in 2017

In September of 2019, the GPMB commissioned a white paper with JHCHS titled "Preparedness for a High Impact Respiratory Pandemic"

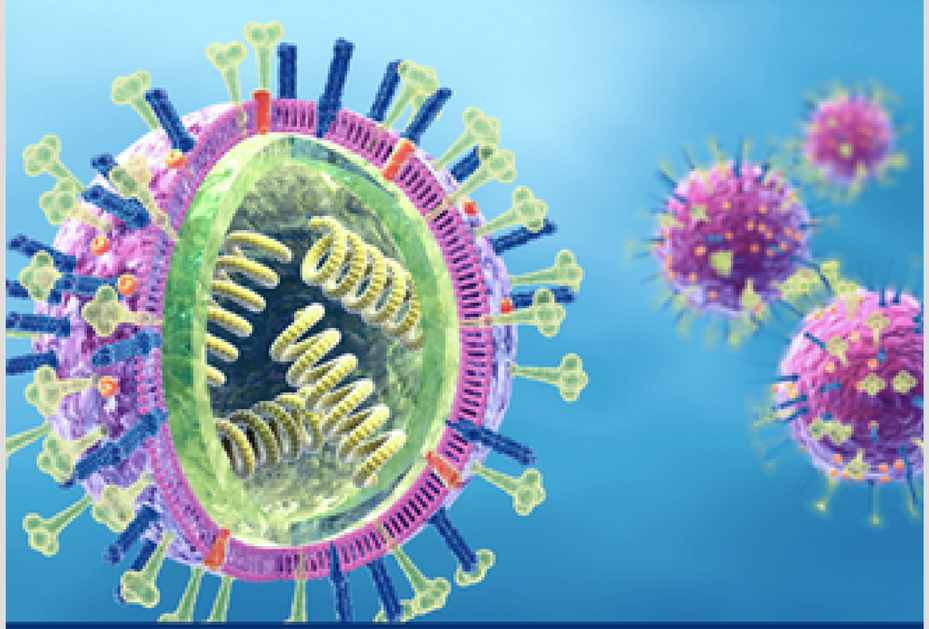
The writers of this document also wrote the script for Event 201, less than one month later.

Founding Board Member for GPMB at the time of the paper's commissioning was NIAID Director Anthony Fauci.

A World at Risk: GPMB 2019 Annual Report



A World at Risk: GPMB 2019 Annual Report



Johns Hopkins Center for Health Security

Preparedness for a High-Impact Respiratory Pathogen Pandemic

September 2019

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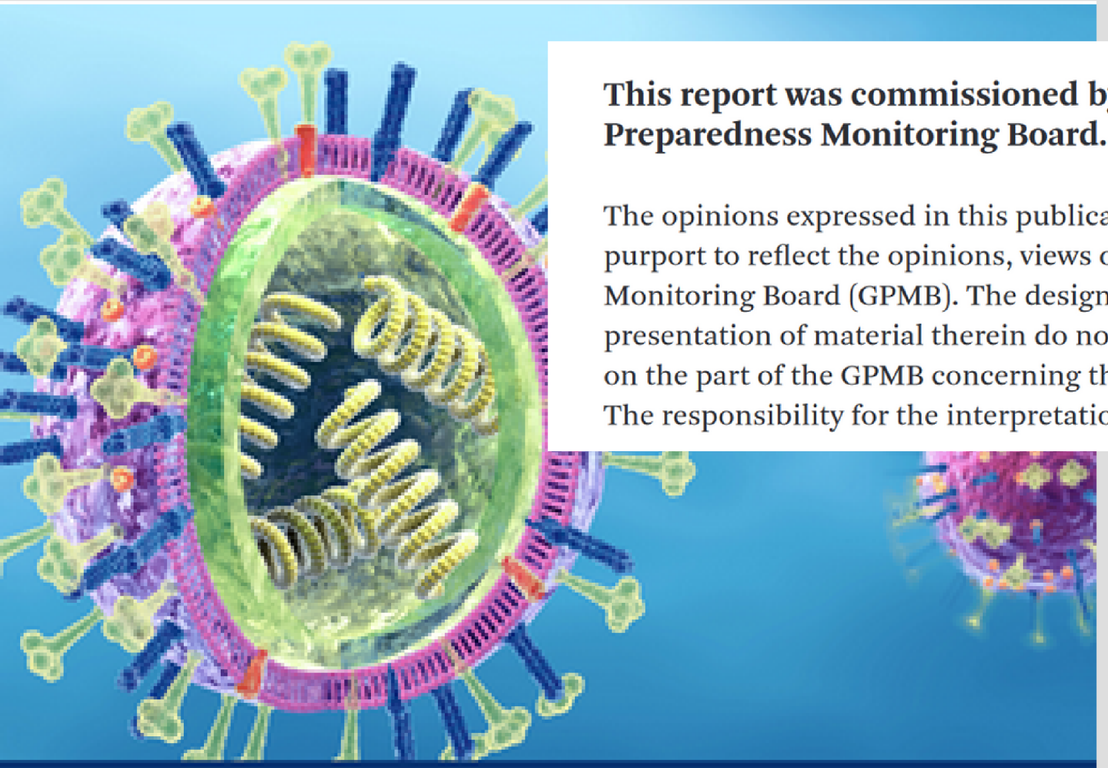
Preparedness for a High-Impact Respiratory Pathogen Pandemic

Johns Hopkins Center for Health Security

10 September 2019 | Publication

This report was commissioned by and prepared for the Global Preparedness Monitoring Board.

The opinions expressed in this publication are those of the authors. They do not purport to reflect the opinions, views or recommendations of the Global Preparedness Monitoring Board (GPMB). The designations employed in this publication and the presentation of material therein do not imply the expression of any opinion whatsoever on the part of the GPMB concerning the legal status of any country, area or territory. The responsibility for the interpretation and use of this publication lies with the reader.



Johns Hopkins Center for Health Security

Preparedness for a High-Impact Respiratory Pathogen Pandemic

September 2019

Johns Hopkins Bloomberg School of Public Health | Center for Health Security

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Dr Anthony S. Fauci



Director, National Institute of Allergy and Infectious Diseases, USA

Biography

Anthony S. Fauci, M.D. is director of the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health, where he oversees an extensive research portfolio focused on infectious and immune-mediated diseases. He serves as one of the key advisors to the White House and Department of Health and Human Services on global HIV/AIDS issues, and on initiatives to bolster medical and public health preparedness against emerging infectious disease threats. He is the winner of numerous prestigious awards including the Presidential Medal of Freedom, the National Medal of Science and the Lasker Award for Public Service.

Background documents



10 SEPTEMBER 2019

Advancing epidemics R&D to keep up with a changing world: Progress, challenges and...

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10 September 2019

The state of governance and coordination for health emergency preparedness and response

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Thematic paper on the status of country preparedness capacities

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10 September 2019

Preparedness for a High-Impact Respiratory Pathogen Pandemic

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10 September 2019

Pandemic Preparedness Financing: Status Update

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EVENT 201: HOSTED BY JOHNS HOPKINS CENTER FOR HEALTH SECURITY, THE WORLD ECONOMIC FORUM, THE BILL & MELINDA GATES FOUNDATION, OCTOBER 2019.

When/where

Friday, October 18, 2019
8:45 a.m. – 12:30 p.m.
The Pierre hotel
New York, NY

EVENT 201
A GLOBAL PANDEMIC EXERCISE

Audience

An invitation-only audience of nearly 130 people attended the exercises, and a livestream of the event was available to everyone. Video coverage is available here.

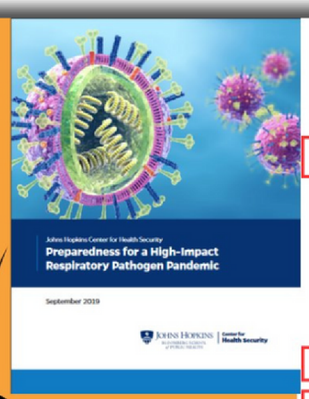
Exercise team

Eric Toner, MD, is the exercise team lead from the Johns Hopkins Center for Health Security. Crystal Watson, DrPH, MPH and Tara Kirk Sell, PhD, MA are co-leads from the Johns Hopkins Center for Health Security. Ryan Morhard, JD, is the exercise lead from the World Economic Forum, and Jeffrey French is the exercise lead for the Bill and Melinda Gates Foundation.

Exercise team members are Tom Inglesby, MD; Anita Cicero, JD; Randy Larsen, USAF (retired); Caitlin Rivers, PhD, MPH; Diane Meyer, RN, MPH; Matthew Shearer, MPH; Matthew Watson; Richard Bruns, PhD; Jackie Fox; Andrea Lapp; Margaret Miller; Carol Miller; and Julia Cizek.

Event 201 was supported by funding from the Open Philanthropy Project.

Vs



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Margaret Miller, Director of Communications

THE EVENT 201 [OCT 2019] EXERCISE WAS WRITTEN BY 11 OF THE SAME AUTHORS AS THE GPMB 'S "PREPAREDNESS FOR A HIGH-IMPACT RESPIRATORY PATHOGEN PANDEMIC REPORT



VIRUS 201

Johns Hopkins Center for Health Security Calls for Funding for New Initiatives to Rapidly Develop Medical Countermeasures for Novel Infectious Diseases in Months, Not Years

Published **April 30, 2020**

CENTER NEWS

April 30, 2020 – Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

The Center for Health Security calls for a new dedicated Virus 201 strategy and program, and funding must be created to achieve this goal through the HHS Biomedical Advanced Research and Development Authority (BARDA) and the DOD Joint Program Executive Office for Chemical and Biological Defense (JPEO). This strategy should not compete with or cannibalize other important medical countermeasure development efforts focused on specific known threats, and it should involve other innovative agencies like DARPA and In-Q-Tel.

https://centerforhealthsecurity.org/2020/johns-hopkins-center-for-health-security-calls-for-funding-for-new-initiatives-to-rapidly-develop-medical-countermeasures-for-novel-infectious

WORLD BANK GROUP
Health, Nutrition & Population

Pandemic Preparedness Financing

STATUS UPDATE

September 2019

This report was commissioned by and prepared for the Global Preparedness Monitoring Board. The opinions expressed in this publication are those of the authors. They do not purport to reflect the opinions, views or recommendations of the Global Preparedness Monitoring Board (GPMB). The designations employed in this publication and the presentation of material therein do not imply the expression of any opinion whatsoever on the part of the GPMB concerning the legal status of any country, area or territory. The responsibility for the interpretation and use of this publication lies with the reader.

This report was commissioned by and prepared for the Global Preparedness Monitoring Board. The opinions expressed in this publication are those of the authors. They do not purport to reflect the opinions, views or recommendations of the Global Preparedness Monitoring Board (GPMB). The designations employed in this publication and the presentation of material therein do not imply the expression of any opinion whatsoever on the part of the GPMB concerning the legal status of any country, area or territory. The responsibility for the interpretation and use of this publication lies with the reader.

Background

The Global Preparedness Monitoring Board intends to provide an authoritative, independent, comprehensive, inclusive overview of the state of global preparedness for health crises by issuing an annual report each year, commissioning special reports, and promoting global action. This first annual report will focus as its starting point updates on the status of implementation of recommendations that emerged after the West Africa Ebola Virus Disease outbreak in 2014–15 in several domains—country preparedness capacity, pandemic preparedness financing, governance and coordination of health emergency preparedness, response, research and development, and putting communities at the center of all preparedness—as well as an examination of lessons learned from 2014–15 and current Ebola outbreaks, and risks associated with rapidly moving, high impact pandemics due to respiratory pathogens. It is envisaged that the status of preparedness will be updated each year with new data and information. The report will draw on materials that other monitoring or oversight bodies regularly produce (e.g., World Health Organization's Health Emergencies Program Independent Oversight and Advisory Committee reports), reports that the Global Preparedness Monitoring Board commissions to address topics that are not otherwise being reviewed, and other relevant published and unpublished reports.

This paper discusses pandemic preparedness financing and cuts across the dimensions of country capacity strengthening, governance and coordination, and research and development. The report is intended for a wide audience including policy-makers, government officials, financing agencies, and the public.

Figures

Figure 1: Metabiota Epidemic Preparedness Index (EPI) by Income Group—188 Countries 2
Figure 2: International Development Association (IDA) Commitments to Preparedness in Regional Health, Nutrition and Population Global Practice Projects, 2010–2020 7
Figure 3: World Health Organization (WHO) Health Emergency Program Budget and Expenditures, Not Including Contingency Fund for Emergencies and Pandemic Influenza Preparedness 12
Figure 4: Macroeconomic Indicators and Preparedness Scatterplots 16
Figure 5: Average National Action Plan for Health Security Cost Per Capita 17
Figure 6: Share of National Action Plan for Health Security Costs Across Joint External Evaluation 19 Technical Areas 18
Figure 7: Development Assistance for Health for Pandemic Preparedness, 2014 to 2018 20
Figure 8: Vietnam Health Security Expenditures by 19 Technical Areas, 2016 22

Tables

Table 1: Joint External Evaluation (JEE) Scores—76 Countries 2
Table 2: Summary Status of Financing Recommendations by Theme 4

BBC

Home News Sport Business Innovation Culture Travel Earth Video Live

Some experts say the true origins of Covid - which has killed nearly seven million people worldwide - may never be known.



https://www.bbc.com/news/world-us-canada-66005240

BBC

Home News Sport Business Innovation Culture Travel Earth Video Live

The ODNI report was released on Friday night after Congress passed a bill in March giving US intelligence 90 days to declassify what it knew about the Wuhan Institute of Virology (WIV).

"The Central Intelligence Agency and another agency remain unable to determine the precise origin of the Covid-19 pandemic, as both (natural and lab) hypotheses rely on significant assumptions or face challenges with conflicting reporting," **said the 10-page report**.

Four agencies believe the virus was transferred from animals to humans, said the findings.

Two other agencies - the Energy Department and the FBI - continue to believe that the virus leaked from a lab.

The findings said the US intelligence community still could not rule out the possibility that the virus came from a laboratory.

Susan Weiss



Susan R. Weiss is an American microbiologist who is a Professor of Microbiology at the Perelman School of Medicine at the University of Pennsylvania. She holds vice chair positions for the Department of Microbiology and for Faculty Development.[1] Her research considers the biology of coronaviruses, including SARS, MERS and SARS-CoV-2. As of March 2020, Weiss serves as Co-Director of the University of Pennsylvania/Penn Medicine Center for Research on Coronavirus and Other Emerging Pathogens.[2]

Alma mater	Brandeis University (BA) Harvard University (PhD)
Known for	Coronavirus

Papers published on a yearly basis

2021	2020	2019	2018	2017	2016	2015	2014	2013	2012	2011
2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000
1999	1998	1997	1996	1995	1994	1993	1992	1991	1990	1989
1988	1987	1986	1985	1984	1983	1982	1981	1980	1978	1977
1976	1975	1974								

Susan Weiss

PANDEMIC PERSPECTIVES

Interview with Susan Weiss

The University of Pennsylvania microbiology professor talks about her 40 years of experience researching coronaviruses.

Episode 249 | May 21, 2020



Susan Weiss

University of Pennsylvania

Other affiliations: University at Albany, SUNY, Wistar Institute, University of California, Thomas Jefferson University, University of California, San Francisco, Harvard University, Emerging Pathogens Institute, Philadelphia College of Osteopathic Medicine, University of California, Berkeley, University of North Carolina at Chapel Hill, Montclair State University read less

Bio: Susan R. Weiss is an academic researcher from University of Pennsylvania. The author has contributed to research in topic(s): Mouse hepatitis virus & Coronavirus. The author has an hindex of 63, co-authored 246 publication(s) receiving 12344 citation(s). Previous affiliations of Susan R. Weiss include University at Albany, SUNY & Wistar Institute.

Topics: Mouse hepatitis virus, Coronavirus, Virus, Viral replication, RNase P

Based on given publications, some of the most influential papers by Susan R. Weiss are:

- "Coronavirus Pathogenesis and the Emerging Pathogen Severe Acute Respiratory Syndrome Coronavirus" published in Microbiology and Molecular Biology Reviews in 2005 with 813 citations.
- "Chapter 4 - Coronavirus Pathogenesis" published in Advances in Virus Research in 2011 with 511 citations.
- "The receptor binding domain of the viral spike protein is an immunodominant and highly specific target of antibodies in SARS-CoV-2 patients" published in Science Immunology in 2020 with 424 citations.
- "Systematic Assembly of a Full-Length Infectious cDNA of Mouse Hepatitis Virus Strain A59" published in Journal of Virology in 2002 with 285 citations.
- "The group-specific murine coronavirus genes are not essential, but their deletion, by reverse genetics, is attenuating in the natural host" published in Virology in 2002 with 226 citations.

Note: This is not an exhaustive list and there may be other influential papers by the author.

W. Ian Lipkin



the epidemic.[29] Lipkin was requested to assist with the investigation by Chen Zhou, vice president of the Chinese Academy of Sciences and Xu Guanhua, minister of the Ministry of Science and Technology in China to "assess the state of the epidemic, identify the gaps in science, and develop a strategy for

In 2016, the Chinese government awarded him the International Science and Technology Cooperation Award, the nation's top science honor for foreign scientists,[37] and in January 2020, it awarded him a medal marking the People's Republic of China's 70th Anniversary, both awards for his work during the 2002–2004 SARS outbreak and in strengthening China's public health system.[38]

On January 29, 2020, Lipkin flew into Guangzhou, China to learn about the outbreak of SARS-CoV-2.[59] Lipkin met with the epidemiologist and pulmonologist Zhong Nanshan,[60] the lead advisor to the Chinese government during the outbreak.[61] Lipkin also worked with the China CDC to access blood samples from across the country for further study into the origin and spread of the virus.[62] Lipkin did not travel to Wuhan, the epicenter of the outbreak, due to fears that this would prevent him from returning to the United States.[63] On returning to the United States, Lipkin self-quarantined for 14 days.[64] Lipkin later contracted SARS-CoV-2 in New York City,[65] refusing to go to hospital and treating himself with hydroxychloroquine at home.[58]

On the Wikipedia Page for "Coronavirus researchers"

There are 19 names scientists. 5/19 are well recognized and often discussed.

4/19 are slightly less familiar. 1/19 were authors in the "Proximal Origins" paper.

Not named however is Holmes, Baric or Mclellan.

Highly Discussed

Less Familiar

Author in "Proximal Origins"

Pages in category "Coronavirus researchers"

A
- June Almeida
- Andrea Ammon

D
- Peter Daszak
- Mark R. Denison

F
- Neil Ferguson (epidemiologist)

G
- George F. Gao
- Guan Yi

L
- Yee-Sin Leo
- Li Lanjuan
- Linfa Wang
- W. Ian Lipkin

O
- Dion O'Neale

P
- Stanley Perlman

R
- Caitlin Rivers
- Michael J. Ryan (doctor)

S
- Shi Zhengli

W
- Susan Weiss

Y
- Yuen Kwok-yung

Z
- Zhong Nanshan

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WayBackMachine
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24 captures
13 Nov 2020 - 27 Nov 2023
Go
OCT NOV MAR
13
2019 2020 2022

Category:Coronavirus researchers

From Wikipedia, the free encyclopedia

Pages in category "Coronavirus researchers"

The following 75 pages are in this category, out of 75 total. This list may not reflect recent changes (learn more).

A

- Ai Fen
- June Almeida
- Andrea Ammon
- Bruce Aylward

B

- Oni Blackstock
- Luciana Borio
- Lydia Bourouiba
- Sylvie Briand
- Caroline Buckee
- Roberto Burioni

C

- George F. Gao
- Johan Giesecke
- Jaqueline Goés de Jesus
- Guan Yi

H

- History of coronavirus
- Claire Hopkins

I

- Kentaro Iwata

J

- Indra Joshi

K

- Rebecca Katz

P

- Alexandra Phelan

R

- Angela Rasmussen
- Caitlin Rivers
- Robert Rodriguez (physician)
- Michael J. Ryan (doctor)

S

- Renee Salas
- Hanneke Schuitemaker
- David M. Smith (virologist)
- Roberto Stella
- Soumya Swaminathan (scientist)

INTERNET ARCHIVE
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https://en.wikipedia.org/wiki/Category:Coronavirus_researchers
24 captures
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2019 2020 2022

- Müge Çevik
- Nishi Chaturvedi
- Sherry Chou
- Kizzmekia Corbett
- Corona Rintawan
- Chinazo Cunningham

D

- Susan Daniel
- Donna E. Davies
- Natalie Dean
- Sara Del Valle
- Tao Dong
- Katie Doores
- Christian Drosten

E

- Katie Ewer

F

- Neil Ferguson (epidemiologist)
- Dale Fisher
- Rebecca Katz
- Alexander Kekulé
- Sabra Klein
- Marian Knight
- Colleen Kraft

L

- Li Lanjuan
- Xie Linka
- W. Ian Lipkin
- Marc Lipsitch
- Liu Wen (doctor)

M

- Ma Xiaowei
- Maia Majumder
- Yvonne Maldonado
- Samira Mubareka
- Eleanor Murray

N

- Catherine Noakes

O

T

- Anders Tegnell
- Marta Tufet

V

- Maria Van Kerkhove
- Cécile Viboud

W

- Louise Wain
- Wang Chen (physician)
- Wang Guangfa
- Crystal Watson
- Susan Weiss

Y

- Li-Meng Yan
- Yuen Kwok-yung

Z

- Zeng Guang
- Zhang Wenhong
- Zhong Nanshan



The Current webpage on Wikipedia for Coronavirus Researchers has 18 people listed.

The *Archived 2020* webpage on Wikipedia for Coronavirus Researchers has 75 people listed.

Where did the other 57 Coronavirus Researchers go?



Mikael Dolsten, M.D., Ph.D.

Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer Inc.

Mikael Dolsten focuses on advancing Pfizer's scientific breakthrough leadership in small-molecule medicines, biotherapeutics, gene therapies and vaccines. He is a member of the Executive Leadership Team and the company's Portfolio Management Team, which governs major pipeline investments and strategic end-to-end R&D priorities.

Mikael leads the Worldwide Research, Development and Medical (WRDM) organization at Pfizer, which is responsible for the development of all compounds through proof of concept, and provides pharmaceutical sciences, safety and medical support to the entire R&D pipeline and all marketed medicines and vaccines. WRDM comprises all Pfizer research units, including Oncology, Internal Medicine, Inflammation & Immunology, Vaccines and Rare Disease, as well as the Centers for Therapeutic Innovation. The Vaccines R&D team leads scientific efforts from discovery through registration of novel vaccines. Mikael also has worldwide responsibility for Pfizer's medical, safety and external R&D innovation, as well as science-based teams in pharmaceutical sciences, drug safety R&D, and large and small molecule discovery and development. Prior to joining Pfizer in

Mikael earned his Ph.D. in tumor immunology and M.D. from the University of Lund in Sweden, where he was Adjunct Professor in Tumor Immunology and is a Visiting Professor to advise on science and technology strategies. He is a member of the boards of Agilent Technologies, Research!America, and Vimian. Additionally, Mikael is a member of the Board of Overseers for the Scripps Research Institute and a Foreign Member of The Royal Swedish Academy of Engineering Sciences. Since 2014, Mikael had co-chaired the Accelerating Medicine Partnership with National Institutes of Health (NIH) Director, Francis S. Collins, and now with Acting Director, Lawrence Tabak. Mikael advised the Obama Administration on regulatory and drug development issues as well as then Vice President Biden's Cancer Moonshot Initiative to accelerate cancer research. Mikael serves on the PhRMA Research & Development Leadership Forum and, until late 2022, served on the PhRMA Foundation Board of Directors. Through 2019, Mikael was a council member of the Government-University-Industry Research Roundtable.

Pfizer Inc.

66 Hudson Boulevard East
New York, NY 10001-2192
United States
212 733 2323
https://www.pfizer.com

Sector(s): **Healthcare**
Industry: **Drug Manufacturers—General**
Full Time Employees: **83,000**

Key Executives

Name	Title	Pay	Exercised	Year Born
Dr. Albert Bourla D.V.M., DVM, Ph.D.	Chairman & CEO	11.72M	N/A	1962
Mr. Frank A. D'Amelio	CFO & Exec. VP	N/A	N/A	1958
Mr. David M. Denton	Chief Financial Officer & Exec. VP	18.19M	N/A	1965
Dr. Mikael Dolsten M.D., Ph.D.	Chief Scientific Officer and Pres of Worldwide Research, Devel. & Medical	5.82M	N/A	1958
Ms. Angela Hwang	Chief Commercial Officer & Pres of Global Biopharmaceuticals Bus.	4.89M	7.7M	1966
Dr. William Pao M.D., Ph.D.	Exec. VP & Chief Devel. Officer	11.26M	N/A	1967

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Company name or number SEARCH

Companies Officers

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RESILIENCE BIOTECHNOLOGIES INC.

Company Number	BC1259445
Status	Active
Incorporation Date	30 July 2020 (almost 3 years ago)
Company Type	BC Company
Jurisdiction	British Columbia (Canada)
Business Number	720950070
Registry Page	https://www.orgbook.gov.bc.ca/entity/...

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2020-07-30 Incorporated

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Recent filings for RESILIENCE BIOTECHNOLOGIES INC.

1 Oct 2020 NOTICE OF ALTERATION

Source *OrgBook BC, https://www.orgbook.gov.bc.ca/search, 1 Jul 2023*

JULY 30 2020

businesswire
A BERKSHIRE HATHAWAY COMPANY

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Resilience Receives USD $164 Million Investment from the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness



RESILIENCE

NATIONAL RESILIENCE, INC.

- **Headquarters:** San Diego, California, US
- **Website:** www.resilience.com
- **CEO:** Rahul Singhvi
- **Employees:** 1,600
- **Organization:** PRI

Release Summary

businesswire
A BERKSHIRE HATHAWAY COMPANY

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Search

Safa'a Al-Rais, Chief Operating Officer at Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI), a subsidiary of National Resilience, Inc. (Resilience), discusses the Canadian Government's CAD 199.2 million ($163.8 million) investment in the site, through the Strategic Innovation Fund. The investment will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.





RESILIENCE

May 18, 2021 12:15 PM Eastern Daylight Time

SAN DIEGO & BOSTON--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company building the world's most advanced biopharmaceutical manufacturing ecosystem, announced that the Government of Canada will invest CAD 199.2 million ($163.8 million), through the Strategic Innovation Fund, in the company's Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI) to modernize and expand production capacity.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases"

Tweet this

This project will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are now being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This partnership with the Government of Canada will help prepare Canada for future pandemics and strengthen the country's biopharmaceutical ecosystem."

"The Government of Canada's top priority is to protect the health and safety of Canadians. Today's contribution to Resilience Biotechnologies Inc. is another important step to support Canada's leadership in the life sciences sector and to build future pandemic preparedness. These investments are also creating well-paying jobs and helping to grow Canada's life sciences ecosystem as an engine

MAY 18 2021

RESILIENCE BIOTECHNOLOGIES INC IS THE ONTARIO BASED SUBSIDIARY OF NATIONAL RESILIENCE INC

THE GOVERNMENT OF CANADA INVESTED $163.8M

Resilience (Durham)

National Resilience manufactures viral vectors, a component of cell and gene therapies.

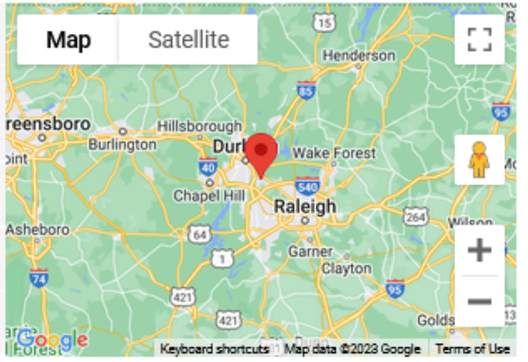
https://resilience.com

1733 T.W. Alexander Drive
Durham NC 27703

Phone (984) 202-0854

County Durham

Region Triangle



Company Details

Company type Bioscience Company	**Year founded** 2020
Employment range in NC 100-199	**US headquarters** California
Global headquarters United States	**Primary site activity** Production and Manufacturing
All company activities Production and Manufacturing	**Core capabilities** Gene Therapy Formulation or Fill and Finish
Potential end market(s) Therapeutics - Gene- and Cell-based Therapies Therapeutics - Large Molecule (biologics) Cancers and other Neoplasms Congenital and Genetic Diseases	

https://bioprocessintl.com › bioprocess-insider › canada-pays-164-million-to-add-resilience

Canada adds Resilience to pandemic prep for $164 - BioProcess .

Canada has called on **Resilience Biotechnologies** to boost local COVID-19 shot capacity. The Canadian Government has given contract development manufacturing organization (CDMO) **Resilience Biotechnologies** $164 million to modernize its recently acquired Ontario plant as par of a wider pandemic preparedness effort.

https://directory.ncbiotech.org › company › resilience-durham

Resilience (Durham) | North Carolina Biotech Center

National Resilience manufactures viral vectors, a component of cell and gene therapies.

https://www.lobbycanada.gc.ca › app › secure › ocl › lrs › do › vwRg?cno=368948

Registration - In-house Corporation - Commissioner of Lobbying ..

In-house Corporation Details Description of activities **Resilience Biotechnologies** (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics.

https://www.theofficialboard.com › news › resilience-biotechnologies

News at Resilience Biotechnologies - The Official Board

Jun 8, 2022 · **Resilience Biotechnologies** has 2,177 competitors including Eurofins (Luxembourg

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A public directory of organizations registered in BC

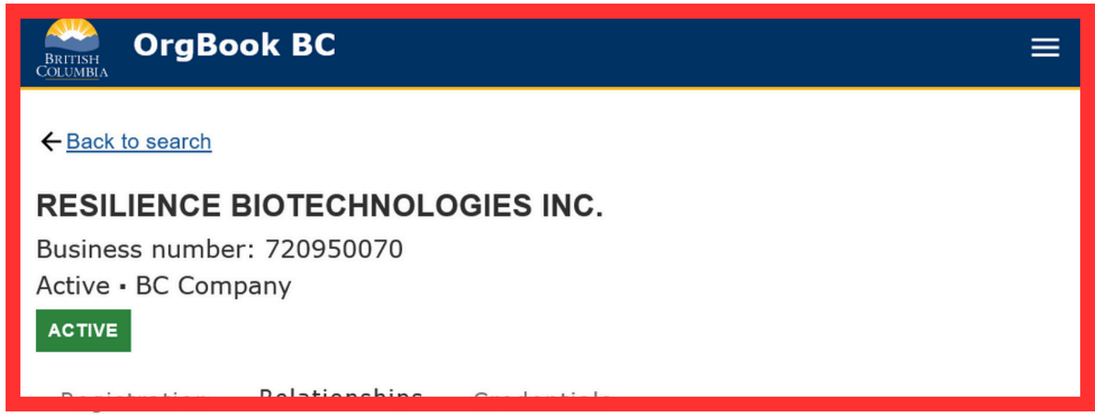
RESILIENCE BIOTECHNOLOGIES INC.

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RESILIENCE BIOTECHNOLOGIES INC.
BC Company
Business number: 720950070
Incorporation number: BC1259445



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Registration

RESILIENCE BIOTECHNOLOGIES INC. is a
BC Company

Incorporation number: BC1259445
Registered on: Jul 29, 2020
Business name effective: Jul 29, 2020

Registration - In-house Corporation

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Resilience Biotechnologies, Inc. / Sankalp Vashishtha, Vice President / General Manager

Registration Information

In-house Corporation name: **Resilience Biotechnologies, Inc.**
Responsible Officer Name: **Sankalp Vashishtha, Vice President / General Manager**
Responsible Officer Change History
Initial registration start date: **2021-02-24**
Registration status: **Active**
Registration Number: **953057-368948**

Associated Communications

Total Number of Communication Reports: **0**

Monthly communication reports in the last 6 months: **0**

Registration versions: 5 of 5: 2023-02-20 to present

Version 5 of 5 (2023-02-20 to present)

Lobbying Information | In-house Corporation Details | Lobbyists Details

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Vice President / General Manager

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Chief Operating Officer, interim

Government funding

End date of the last completed financial year: 2021-12-31

Government Institution	Funding Received in Last Financial Year	Funding Expected in Current Financial Year
National Research Council (NRC)	$2,063,196.23	Yes

In-house Corporation Contact Information

Address:
2585 Meadowpine Blvd.
Mississauga, ON L5N 8H9
Canada

Telephone number: 905-286-6200

Parent Company Information

- National Resilience, Inc.
  - 9310 Athena Circle, Suite 130
    La Jolla, CA 92037
    United States of America

Subsidiary Beneficiary Information

Resilience Biotechnologies, Inc. does not have any subsidiaries that could have a direct interest in the outcome of the undertaking

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ORGANIZATION

Therapure Biopharma

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About

Therapure is an integrated Contract Development and Manufacturing Organization.

Acquired by
3SBio Inc.

Mississauga
251-500
Private
www.therapurebio.com/

Highlights

Contacts
54

Employee Profiles
1

Similar Companies
3

Recent News & Activity

News • Aug 11, 2020
PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017
3SBio Inc. acquired Therapure Biopharma for $290,000,000
Discover more acquisitions

Details

Industries
Manufacturing

Founded Date
2008

Operating Status
Active

Company Type
For Profit

Contact Email
info@therapurebio.com

Phone Number
1(905)286-6200

At Therapure Biopharma Inc. they're specialists in biologics therapeutics, and they act on a passion for enhancing patient care through their three divisions: Therapure Biomanufacturing, Therapure Innovations and Therapure Biologics.

Recent News & Activity

Number of Articles
1

News • Aug 11, 2020
PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017
3SBio Inc. acquired Therapure Biopharma for $290,000,000
Discover more acquisitions

M&A Details

Therapure Biopharma was acquired by 3SBio Inc. for $290M on Sep 3, 2017.

Transaction Name
Therapure Biopharma acquired by ...

Acquired by
3SBio Inc.

Announced Date
Sep 3, 2017

Price
$290M

3SBio Inc.

Summary | Financials | People

Details

Industries
Biotechnology

Headquarters Regions
Asia-Pacific (APAC)

Founded Date
1993

Founders
Dr. Jing Lou

Operating Status
Active

Last Funding Type
Post-IPO Equity

Legal Name
Sunshine Guojian Pharmaceuticals (Shanghai) Co., Ltd.

Stock Symbol
NASDAQ:SSRX

Company Type
For Profit

Number of Exits
1

Phone Number
+862425386000

3SBio is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China. Its focus is on addressing large markets with significant unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious diseases.With headquarters and GMP-certified manufacturing facilities in Shenyang, PRC, 3SBio employs over 800 people.

Frequently Asked Questions

Where is **3SBio Inc.**'s headquarters? **3SBio Inc.** is located in **Shenyang, Liaoning, China**.

Who invested in **3SBio Inc.**? **3SBio Inc.** is funded by **Numab**.

How much funding has **3SBio Inc.** raised to date? **3SBio Inc.** has raised **CHF15M**.

When was the last funding round for **3SBio Inc.**? **3SBio Inc.** closed its last funding round on **Dec 12, 2019** from a **Post-IPO Equity** round.

Who are **3SBio Inc.**'s competitors? Alternatives and possible competitors to **3SBio Inc.** may include **Brainsway**, **Innovative Cellular Therapeutics**, and **MabSpace Biosciences**.

Resilience Biotechnologies Inc.

(0 Reviews)

1733 TW Alexander Dr
Durham, NC 27703

Header	Company	Date	News Type
Proposed Initial Public Offering			
Therapure Biopharma Launches Biologics Division as Evolve Biologics, an Innovative Plasma-Derived Therapeutics Company	Evolve Biologics Inc. Resilience Biotechnologies Inc.	2018-03-23	Financial News
Therapure Biopharma Inc. Wins the Mississauga Board of Trade's 2017 Business Awards of Excellence	Resilience Biotechnologies Inc.	2017-11-17	Other Company News
Therapure Biopharma Inc. Ranks No. 115 on the 2017 PROFIT 500 – Its 4th Consecutive Year on the List	Resilience Biotechnologies Inc.	2017-09-27	Other Company News
3SBio Accelerates Expansion of Its Global Biologics Platform by Acquiring the Canadian Biomanufacturing Business of Therapure	3SBio Inc. CPE Funds Resilience Biotechnologies Inc.	2017-09-03	Financial News
Therapure Biomanufacturing Receives 2017 CMO Leadership Individual Attribute Awards for Capabilities and Staff Characteristics	Resilience Biotechnologies Inc.	2017-04-05	Other Company News
For a Third Consecutive Year Therapure Biopharma Inc. Ranks in the PROFIT 500 List of the Fastest-Growing Companies in Canada and Ranks 10th in the GTA Manufacturing Sector	Resilience Biotechnologies Inc.	2016-09-30	Other Company News

Company News

Company Resilience Biotechnologies Inc. ×

Company News

Header	Company	Date	News Type
U of T Home to New Hub That Will Strengthen Canada's Pandemic Preparedness and Increase Biomanufacturing Capacity	Centre for Commercialization of Regenerative Medicine adMare BioInnovations CoVaRR-Net Cyclica Inc. Cytiva National Research Council Canada Providence Therapeutics Holdings Inc. Resilience Biotechnologies Inc. Sanofi SA Sartorius Stedim Biotech S.A. University of Saskatchewan University of Toronto	2023-03-02	Financial News
Evolve Biologics Announces Site Selection, Land Purchase and Groundbreaking Ceremony for First Manufacturing Facility in Sachse, Texas	Evolve Biologics Inc. National Resilience, Inc. Resilience Biotechnologies Inc.	2021-12-06	Product News
Resilience Receives USD $164 Million Investment From the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness	National Resilience, Inc. Resilience Biotechnologies Inc. Strategic Innovation Fund (SIF)	2021-05-18	Financial News

RESILIENCE GOVERNMENT SERVICES, INC BRANCH

Company Number	F16440265
Status	Incorporated
Incorporation Date	31 March 2015 (over 8 years ago)
Company Type	FOREIGN CORPORATION
Jurisdiction	Maryland (US)
Branch	Branch of OLOGY BIOSERVICES, INC. (Delaware (US))
Registered Address	13200 NW NANO COURT ALACHUA 32615 FL United States
Previous Names	NANOTHERAPEUTICS, INC OLOGY BIOSERVICES, INC
Business Classification Text	03 ORDINARY BUSINESS - STOCK
Agent Name	CSC-LAWYERS INCORPORATING SERVICE
Agent Address	CSC-LAWYERS INCORPORATING SERVICE, COMPANY, 7 ST. PAUL STREET, SUITE 820, BALTIMORE, MD, 21202
Directors / Officers	CSC-LAWYERS INCORPORATING SERVICE, agent
Registry Page	https://egov.maryland.gov/BusinessExp...

Recent filings for RESILIENCE GOVERNMENT SERVICES, INC

Latest Events

- **2022-05-01 - 2022-05-31** Change of name from 'OLOGY BIOSERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC.'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'

See all events

Corporate Grouping USER CONTRIBUTED

None known. Add one now?

See all corporate groupings

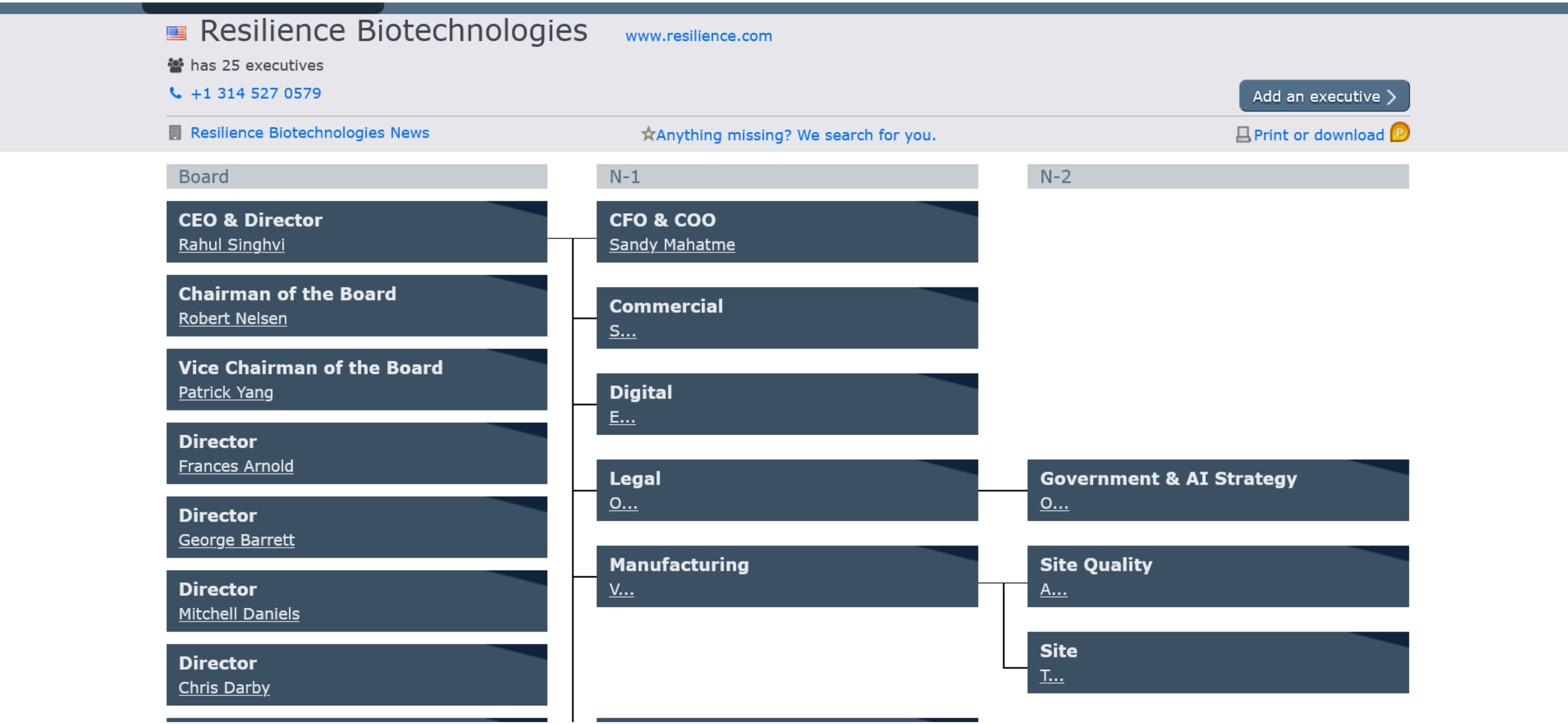
Similarly named companies

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(Florida (US), 19 Jun 2009-)*

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(California (US), 22 Mar 2017-)*

Links:

https://www.theofficialboard.com/org-chart/resilience-biotechnologies



CISA
CYBERSECURITY
ADVISORY
COMMITTEE

REPORT TO THE CISA DIRECTOR

Technical Advisory Council

Vulnerability Discovery and Disclosure Recommendations

June 22, 2022

Introduction:

The Technical Advisory Council Subcommittee was established to leverage the imagination, ing
technical experts from diverse background and experiences for the good of the nation. The sub
to evaluate and make recommendations tactical and strategic in nature. These Cybersecurity A
(CSAC) recommendations for the June Quarterly Meeting focus on vulnerability discovery and d

CSAC conducted interviews with sector-specific agencies such as the Food and Drug Administrati
vendors, and CISA staff to determine the current state of vulnerability discovery and disclosure pr
government and industry and provide meaningful recommendations

CISA
CYBERSECURITY
ADVISORY
COMMITTEE

Acknowledgements:

Technical Advisory Council Members:

Mr. Jeff Moss, Subcommittee Chair, DEF CON Communications

Mr. Dino Dai Zovi, Security Researcher

Mr. Luiz Eduardo, Aruba Threat Labs

Mr. Isiah Jones, National Resilience Inc.

Mr. Kurt Opsahl, Electronic Frontier Foundation

Former Members of the Board of Directors



Dr Moncef Slaoui

Independent member of the Board of Directors of Lonza Group Ltd (April 2020 until May 2020)

Dr Moncef Slaoui brings to Lonza extensive experience from his career with GlaxoSmithKline spanning nearly 30 years. In this time, he held a number of leadership positions, including Member of the Board of GSK PLC, Chairman of Pharmaceutical R&D; and Chairman of Global Vaccines. Currently, Dr Slaoui is partner at Medicxi, a venture capital firm specializing in seed, Series A, early stage and late stage life sciences investments; he also sits on various biotechnology companies' boards. Dr Slaoui received his Ph.D. in Molecular Biology and Immunology from Brussels University in 1983. He later received an accelerated Master of Business Administration from IMD in Lausanne (Switzerland) in 1998.

Current activities and functions

Further Mandates:

- Chairman of Monopteros (A Medicxi Company) (since 2018)
- Chairman of Divide & Conquer (A Medicxi Company) (since 2017)
- Chairman of Sutrovax (since 2017)
- Chairman Galvani Bioelectronics (since 2016)
- Chairman of Clasado (since 2017)

Activity:

- Partner at Medicxi (since 2017)

Former activities and functions

- Independent Member of the Board of Directors of Moderna (2017–2020)
- Member of the Advisory Board of the Qatar Foundation (2009–2020)
- Member of the Board of Directors of International AIDS Vaccines Initiatives (2015–2017)
- Member of the Board of GSK PLC (2006–2017)
- Chairman, Global Vaccines of GSK PLC (2009–2017)
- Chairman, Global Research & Development of GSK PLC (2006–2015)
- Various leadership roles in Research & Development including Worldwide Business Development & External Alliances (1988–2003)

Head of OWS, Moncef Slaoui was also a Board of Directors for Lonza who like Resilience manufactured the Moderna C19 vaccine.

Chris Elias
President, Global Development at Bill & Melinda Gates Foundation

Experience

President, Global Development
Bill & Melinda Gates Foundation
Feb 2012 - Present · 11 yrs 6 mos

The Bill & Melinda Gates Foundation's Global Development Division works to identify and fund high-impact solutions that can help hundreds of millions of people lift themselves out of ...see more

President and CEO
PATH
2000 - Jan 2012 · 12 yrs 1 mo

For more than a decade, I served as president and CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world. At PATH, I ex ...see more

Senior Associate, International Programs
Population Council
1990 - 2000 · 10 yrs

As a senior associate, I oversaw all Population Council activities in Thailand, Cambodia, Myanmar, Yunnan, and the Lao PDR, encompassing reproductive health programs, interventions res ...see more

Interests

Top Voices | Companies | Schools

Peter Sands · 3rd
Executive Director at The Global Fund to Fight AIDS, Tuberculosis and Malaria

Bill Gates
Co-chair, Bill & Melinda Gates Foundation
34,786,737 followers



Christopher Elias

President, Global Development Programs, Gates Foundation

Featured on: April 17, 2015

Dr. Elias has been in this role since 2011. He is responsible for all activities outside of the U.S. that are not focused on new medicine development Dr. Elias oversees Global Development's portfolio in Agriculture Development; Family Planning; Financial Services for the Poor; Maternal, Newborn, & Child Health; Polio; Vaccines Delivery; Water, Sanitation & Hygiene; and Special Initiatives. Previously he served as President/CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. Elias currently serves on various advisory boards, including the Nike Foundation and the Duke Global Health Institute. Dr. Elias holds an MD from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an MPH from the University of Washington. medicine) from Creighton/UCSF, MPH from University of Washington.

Pharmaceutical services firm Resilience debuts, with questions

New company pitches itself as a disruptive engineering services firm in biopharmaceutical manufacturing

by ***Rick Mullin***

November 25, 2020 | A version of this story appeared in **Volume 98, Issue 46**



Resilience, a venture-backed biopharmaceutical manufacturing services firm, has made its debut with an announcement of $800 million in the bank, a roster of highly-accomplished leaders, and an intent to develop “powerful new technologies”

As a first step, Resilience has acquired Therapure Biopharma, a biologics services firm in Mississauga, Ontaro, that observers say has been for sale for 3 years. It also purchased an undisclosed protein-based therapy-manufacturing operation in the US, Resilience CEO Rahul Singhvi says. Both deals were closed in October.

In addition, Singhvi says the firm has laboratory space in place in San Diego and a pending deal for lab space in Boston. The company plans to add two more manufacturing sites to its network in 2022. Resilience plans to establish a network of approximately 10 facilities with expertise in biological drug development, says Singhvi, former CEO of the vaccine maker Novavax.

MOST POPULAR I
BUSINESS

What is hand sanitizer, a it keep your hands germ

4 new chemical technolo could make an impact

Is ammonia the fuel of th future?

Lawmaker Who Led TikTok Ban Bill Joins Private Surveillance Firm: Report

Mike Gallagher pushed the bill to ban TikTok because China can "surveil its users." Now, he's resigning and joining an American surveillance firm

BY CHARISMA MADARANG, ANDREW PEREZ

MARCH 22, 2024



Rep. Mike Gallagher after House passed act th

WILLIAMS/CQ-ROLL CALL, INC VIA GETTY IMAGES

REPUBLICAN REP. MI

could effectively ban TikTok within the country — on the basis that China can "surveil its users" — plans to take up a post with the American surveillance company and defense contractor Palantir, *Forbes* reported.

REPUBLICAN REP. MIKE Gallagher, who led the charge on a bill that could effectively ban TikTok within the country — on the basis that China can "surveil its users" — plans to take up a post with the American surveillance company and defense contractor Palantir, *Forbes* reported.

https://www.rollingstone.com/politics/politics-news/mike-gallagher-tiktok-ban-palantir-1234993167/

NEWS 06.14.2021

Dr. Stephen Hahn, 24th U.S. FDA Commissioner and former Chief Medical Executive at MD Anderson, joins Flagship Pioneering as Chief Medical Officer of its Preemptive Medicine and Health Security Initiative

SHARE

Stephen Hahn



Hahn in 2019

24th Commissioner of Food and Drugs

Cambridge, Mass, June 14, 2021 – Flagship Pioneering, the bioplatform innovation company, announced today that Stephen Hahn, M.D. will help lead its Preemptive Medicine and Health Security initiative as Chief Medical Officer, and join Flagship's Senior Leadership Team, effective June 16, 2021. Dr. Hahn served as the U.S. Food and Drug Administration Commissioner from 2019–2021. Prior to joining the FDA, he was the Chief Medical Executive, The University of Texas MD Anderson Cancer Center.

During his time as the 24th Commissioner of the U.S. Food and Drug Administration, Dr. Hahn led the 17,000+ person agency that regulates approximately 20 percent of consumer spending in the United States. He oversaw both COVID and non-COVID regulatory affairs, including therapeutics and vaccine development, devices, diagnostics, and clinical trials.

Stephen Hahn

Article Talk

From Wikipedia, the free encyclopedia

For other people named Stephen Hahn, see Stephen Hahn (disambiguation).

Stephen Michael Hahn (born January 22, 1960) is an American physician who served as the commissioner of food and drugs from 2019 to 2021. Before becoming commissioner, he was an oncologist serving as chief medical executive of the MD Anderson Cancer Center. In 2021, he became chief medical officer at Flagship Pioneering, the venture capital firm that launched Moderna.

https://en.wikipedia.org/wiki/Stephen_Hahn

Receipts

https://cancerletter.com/covid-19-cancer/20210212_4/
https://cen.acs.org/business/outsourcing/Pharmaceutical-services-firm-Resilience-debuts/98/i46
https://ec.europa.eu/commission/presscorner/detail/en/IP_23_3043
https://commission.europa.eu/strategy-and-policy/coronavirus-response_en
https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en
https://insmed.com/annual_report/2020/Insmed_2020_AnnualReport.pdf
https://www.lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=368948
https://www.mississauga.com/news/
https://live.worldbank.org/experts/christopher-elias
https://www.gpmb.org/annual-reports/annual-report-2019
https://www.weforum.org/press/2019/10/live-simulation-exercise-to-prepare-public-and-private-leaders-for-pandemic-response
https://www.biotalent.ca/organizations/resilience-biotechnologies/
https://www.cnn.com/2021/11/12/health/covid-cancer-biontech-ugur-sahin/index.html
https://www.fao.org/3/cc1533en/cc1533en.pdf
https://www.gpmb.org/about-us
https://www.gpmb.org/docs/librariesprovider17/default-document-library/gpmb-manifesto-2023.pdf?sfvrsn=f8ac828b_11
Global Health Summit 2021: https://www.youtube.com/live/JWUIMRPgBuQ?feature=share

Contract ID:	HSHQDC16C00113	**Reference IDV:**	-
Modification Number:	P00008	**Transaction Number:**	0
Award/IDV Type:	DCA Definitive Contract	**Action Obligation ($):**	-$31,658.43
Date Signed:	Oct 19, 2021	**Solicitation Date:**	-
Contracting Agency ID:	7001	**Contracting Agency:**	OFFICE OF PROCUREMENT OPERATIONS
Contracting Office Name:	CWMD ACQ DIV	**PSC Type:**	S
PSC:	B599	**PSC Description:**	SPECIAL STUDIES/ANALYSIS-OTHER
NAICS:	541990	**NAICS Description:**	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES
Entity City:	NEW YORK	**Entity State:**	NY
Entity ZIP Code:	100012320	**Additional Reporting Code:**	-
Additional Reporting Description:	-	**Unique Entity ID:**	TKS7NBB4JDN6
Ultimate Parent Unique Entity ID:	TKS7NBB4JDN6	**Ultimate Parent Legal Business Name:**	ECOHEALTH ALLIANCE INC.
Legal Business Name:	ECOHEALTH ALLIANCE INC.	**CAGE Code:**	3MMU3

Product/Service Code:	B599 **Description:** SPECIAL STUDIES/ANALYSIS- OTHER
Principal NAICS Code:	541990 **Description:** ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHN
Bundled Contract:	Not a bundled requirement
DOD Acquisition Program:	**Description:**
Country of Product or Service Origin:	USA UNITED STATES
Place of Manufacture:	Not a manufactured end product
Domestic or Foreign Entity:	U.S. Owned Business
Recovered Materials/Sustainability:	No Clauses Included and No Sustainability Included **OMB Policy on Sustainable Acquisition**
Information Technology Commercial Category:	Select One
Claimant Program Code:	**Description:**
Sea Transportation:	Select One
GFP Provided Under This Action:	Transaction does not use GFP
Use Of EPA Designated Products:	Not Required

Description Of Requirement:
(Limit 250 characters)
Current: 241

```
Modify Contract HSHQDC-16-C-00113 between DHS/CWMD/OHA and
EcoHealth Alliance Inc  incorporate the following changes:

1. De-obligate funds in the amount of $31,658.43 from CLIN
0002

2. Incorporate closeout concurrence letter and closeout
```

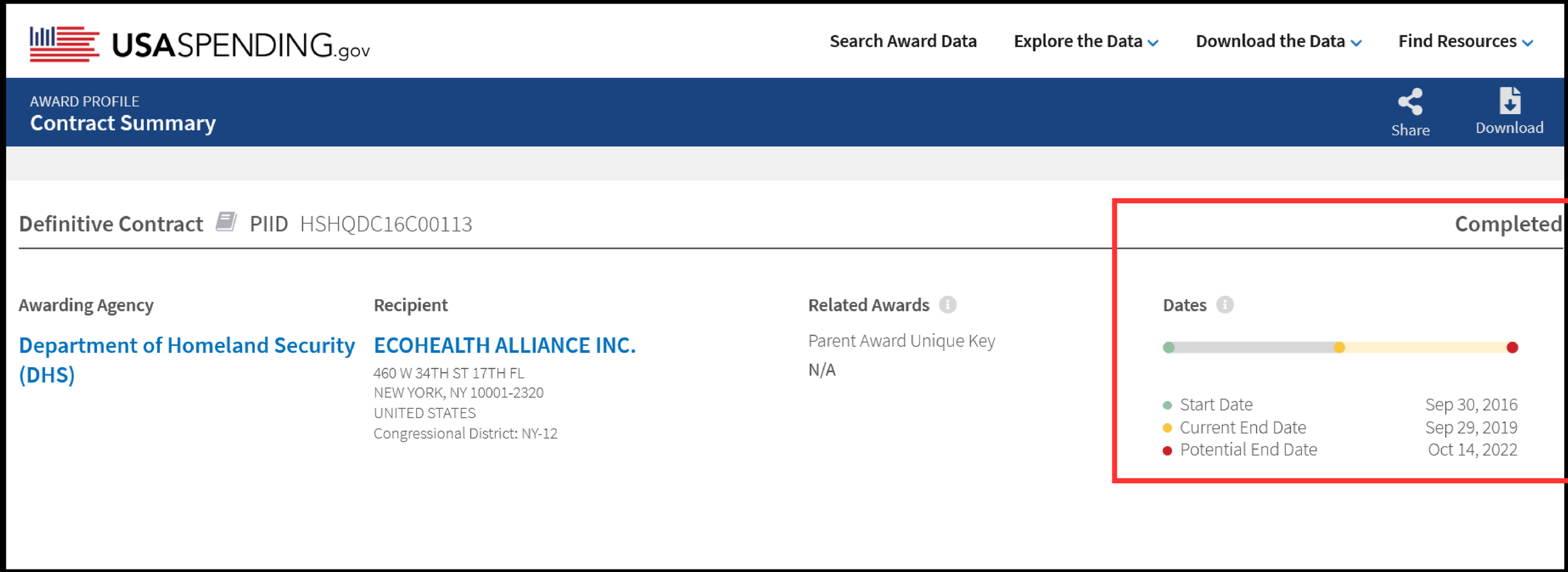
Purchaser Information

Contracting Office Agency ID:	7001	**Contracting Office Agency Name:**	OFFICE OF PROCUREMENT OPERATIONS
Contracting Office ID:	70RWMD	**Contracting Office Name:**	CWMD ACQ DIV
Funding Agency ID:	7062	**Funding Agency Name:**	COUNTERING WEAPONS OF MASS DESTRU
Funding Office ID:	70DWM1	**Funding Office Name:**	ASST SCTY COUNTERING WPNS OF MASS D
Foreign Funding:	Not Applicable		

Entity Information

FAR 4.1102 Exception: Remove Exception

Unique Entity ID:	TKS7NBB4JDN6	**Street:**	460 W 34TH ST 17TH FL
Legal Business Name:	ECOHEALTH ALLIANCE INC.	**Street2:**	
DBAN:		**City:**	NEW YORK
CAGE Code:	3MMU3	**State:**	NY **Zip:** 100012320
		Country:	UNITED STATES
		Phone:	(212) 380-4479
		Fax No:	(212) 380-4465
		Congressional District:	NEW YORK 12



HSHQCD16C00113 on USASPENDING.GOV says the contract began in late 2016, was completed in late 2019 with a potential end date of late 2022.

Awarding Agency

Department of Homeland Security (DHS)

Recipient

ECOHEALTH ALLIANCE INC.

460 W 34TH ST 17TH FL
NEW YORK, NY 10001-2320
UNITED STATES
Congressional District: NY-12

Related Awards

Parent Award Unique Key

N/A

Despite what the political and corporate trends are pushing for, I think its clear to see that the militarization of medical research carries great risk and only reduces transparency.

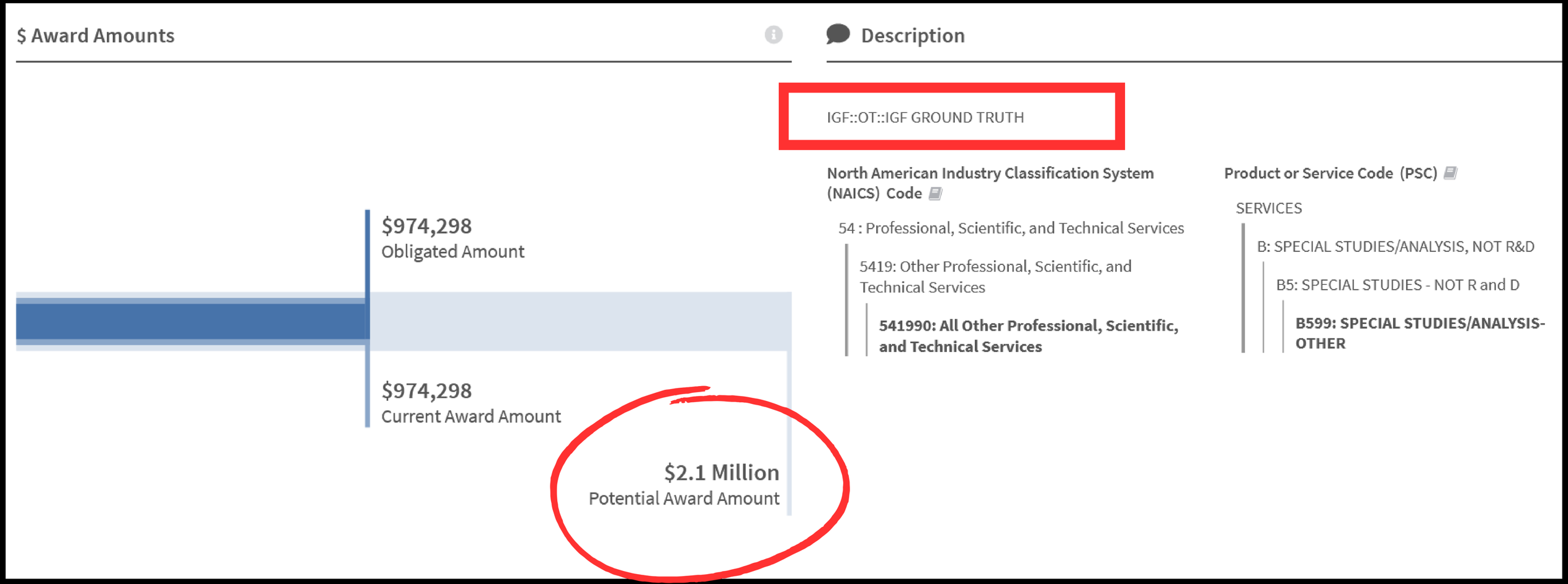
Completed

Dates



Start Date	Sep 30, 2016
Current End Date	Sep 29, 2019
Potential End Date	Oct 14, 2022

The Award Description is stated as "Ground Truth" Which was a multilateral effort to enhance bio-medical research and data



Federal Account	Combined Obligated Amount	Percent of Total	Percent of Total	Funding Agency
OPERATIONS AND SUPPORT, CYBERSECURIT...	$734,685	100%	100%	(DHS) DEPARTMENT OF HOMELAND SECURITY

P00001	11/07/2016	$0	B: SUPPLEMENTAL AGREEMENT FOR WORK WITHIN SCOPE	IGF::OT::IGF GROUND TRUTH
P00002	01/03/2017	$0	M: OTHER ADMINISTRATIVE ACTION	IGF::OT::IGF COR CHANGE FOR THE ECOHEALTH ALLIANCE CONTRACT IN SUPPORT OF NBIC'S ...
P00003	06/14/2017	$390,394	G: EXERCISE AN OPTION	IGF::OT::IGF COR CHANGE FOR THE ECOHEALTH ALLIANCE CONTRACT IN SUPPORT OF NBIC'S ...
P00004	07/18/2017	-$67,112	M: OTHER ADMINISTRATIVE ACTION	IGF::OT::IGF ZERO DOLLAR PR TO REALLOCATE BASE CLIN FUNDING TO OPTION
P00005	08/18/2017	$4,500	C: FUNDING ONLY ACTION	IGF::OT::IGF ZERO DOLLAR PR TO REALLOCATE BASE CLIN FUNDING TO OPTION
P00006	04/10/2018	$0	M: OTHER ADMINISTRATIVE ACTION	IGF::OT::IGF THE PURPOSE OF THIS ZERO DOLLAR MODIFICATION IS TO CHANGE THE COR DUT...
P00007	09/11/2018	$406,902	G: EXERCISE AN OPTION	IGF::OT::IGF THE PURPOSE OF THIS ZERO DOLLAR MODIFICATION IS TO CHANGE THE COR DUT...
P00008	10/19/2021	-$31,658	K: CLOSE OUT	MODIFY CONTRACT HSHQDC-16-C-00113 BETWEEN DHS/CWMD/OHA AND ECOHEALTH ALLIAN...

In the funding transactions we can see that the research originated with the NBIC and later began to collaborate more with DHS's CWMD program.They modified the contract in October 2021, which makes me question- Did they only modify the contract after Covid-19 to ostensibly render the complete details of the work as a "matter of national security" - as a means to conceal details of the C19 origins?

Unique Award Key

Unique Award Key	CONT_AWD_HSHQDC16C00113_7001_-NONE-_-NONE-
Award or IDV Flag	Contract Award
Procurement Instrument Identifier (PIID)	HSHQDC16C00113
Submitting Agency Identifier Code	7001
Parent Award ID (Parent PIID)	--
Parent Agency Identifier Code	--

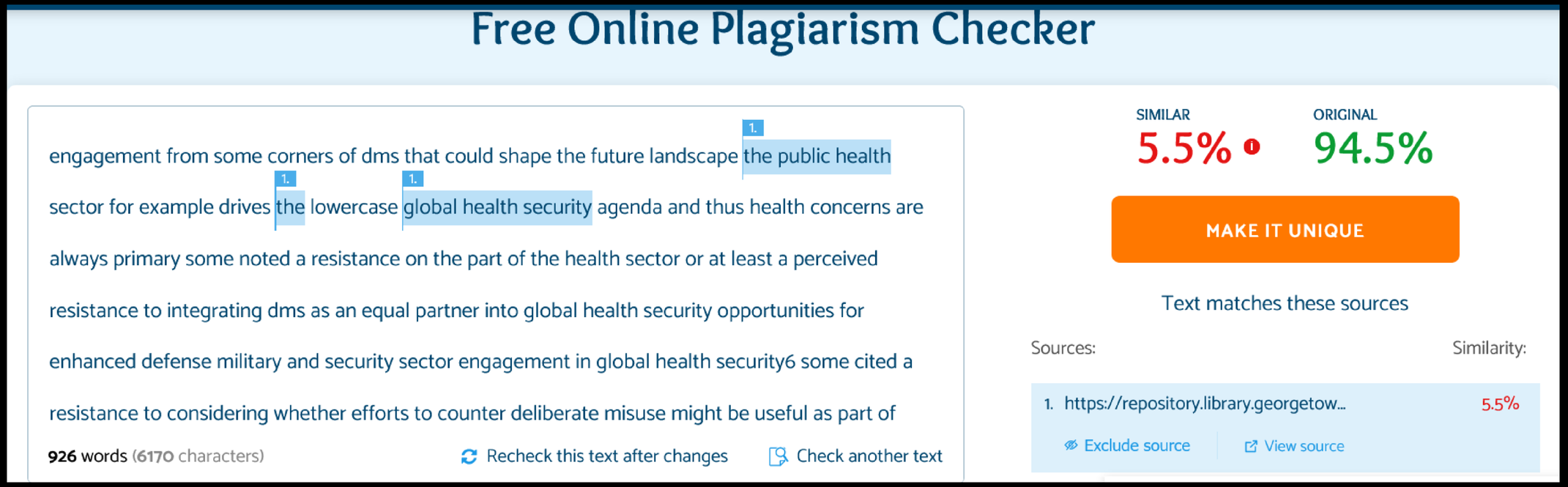
Agency Details

Awarding Agency	Department of Homeland Security (DHS)
Awarding Sub-Agency	Office of Procurement Operations
Awarding Office	CWMD ACQ DIV
Funding Agency	Department of Homeland Security (DHS)
Funding Sub-Agency	Countering Weapons of Mass Destruction
Funding Office	ASST SCTY COUNTERING WPNS OF MASS D

Running the PIID Number through the usaspending.gov website provided more details on the awarding agencies:

Homeland Security, the Office of Procurement Operations & through the sub agency Countering Weapons of Mass Destruction at the Office of the Assistant Secretary for Countering Weapons of Mass Destruction.

A reminder of how impactful the actions that followed 9/11 were- DHS & ProjectBioshield, formed to counter WMD & both came out of legislation created in response to 9/11



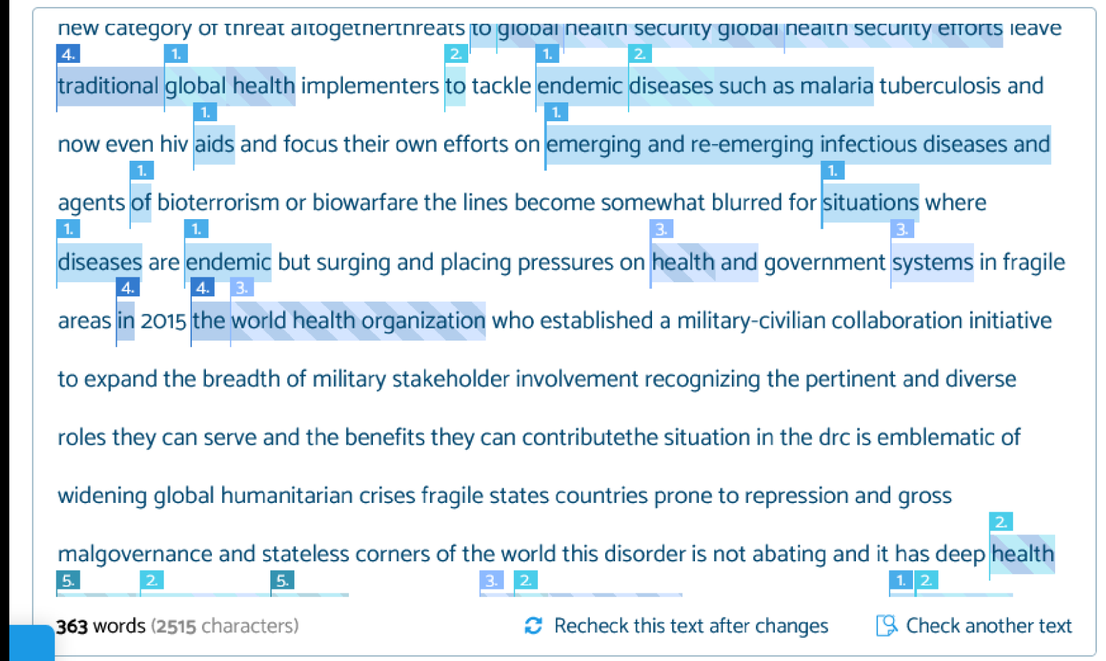
I ran segments of the article through a plagarism checker to determine where else the same rhetoric was possibly employed.

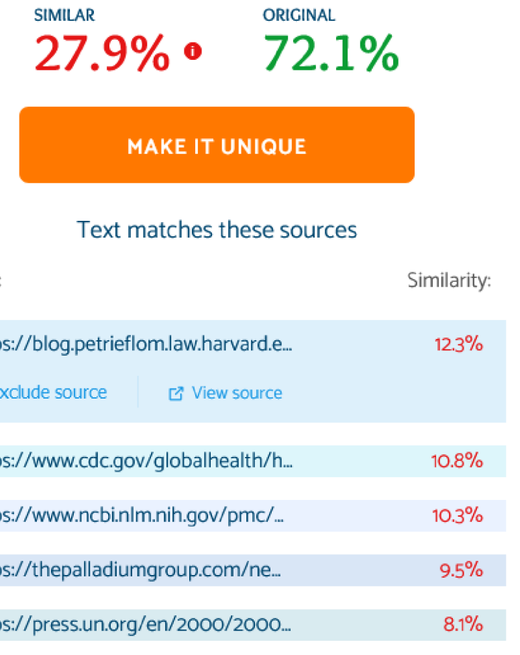
Other than EcoHealth Alliance, the text matched texts in the Georgetown University Repository.

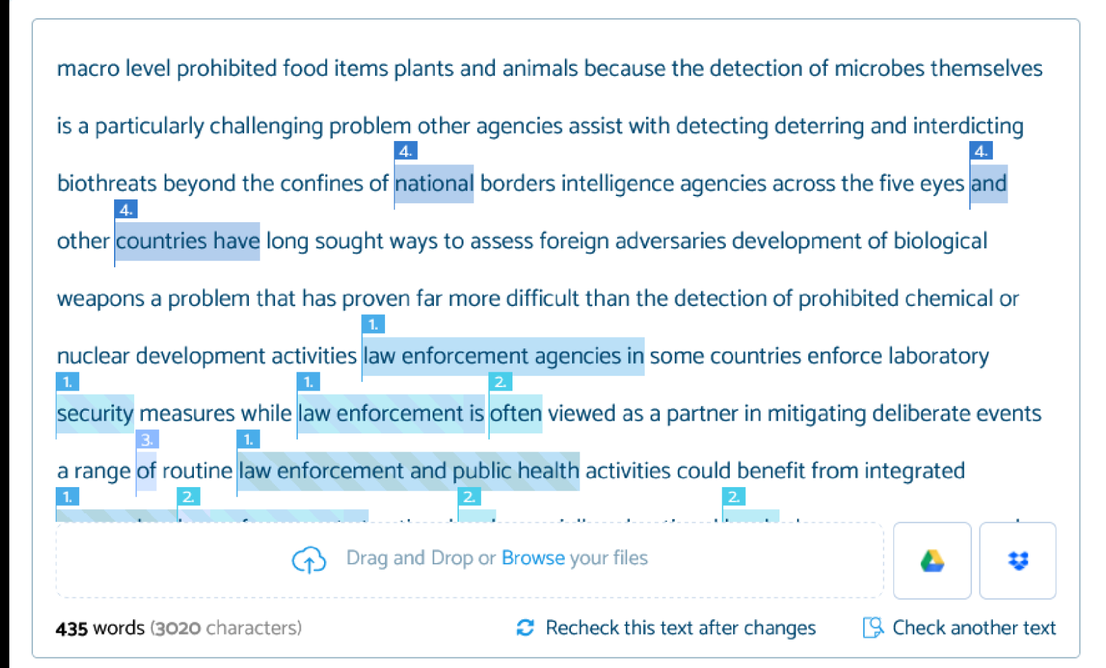


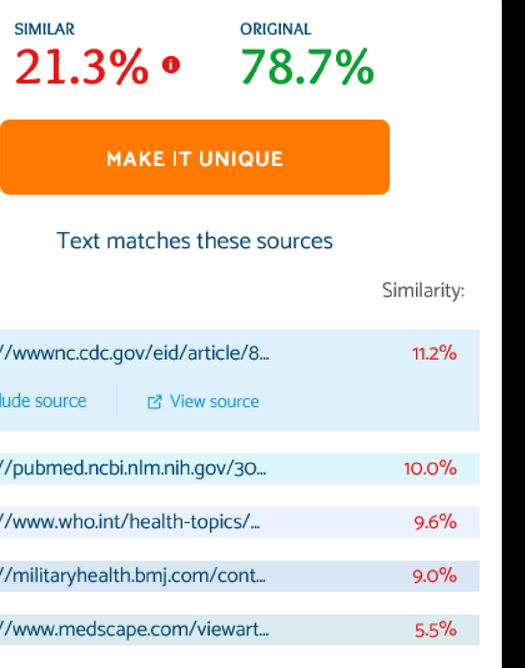
Related institutions/ Shared Rhetoric

- CDC
- NCBI
- Harvard law
- WHO
- MilitaryHealth
- UN
- Medscape









Faculty Scholarship - Department of Microbiology and Immunology

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Creators | Titles | By Creation Date

Dahlgren Memorial Library
THE GRADUATE HEALTH & LIFE SCIENCES RESEARCH LIBRARY AT GEORGETOWN UNIVERSITY MEDICAL CENTER

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Most Recent Submissions



Opportunities for Enhanced Defense, Military, and Security Sector Engagement in Global Health Security

Carlin, Ellen P.; Moore, Mackenzie S.; Shambaugh, Emily; Karesh, William B. (EcoHealth Alliance, 2021)

Despite years of dedicated resources, the global community remains unable to prevent the appearance of emerging infectious diseases and to reliably mount an optimal response when prevention fails. SARS-CoV-2 is the most ...



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Global health security is the bulwark against catastrophic public health events. Building this security is a timely and urgent challenge for the world as it faces an increasing rate of emergent and re-emergent infectious ...

The articles were written by GU Faculty, Two of which are EcoHealth Alliance Members, Ellen P Carlin, & William “Billy” Karesh.

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Author Name
Berthe, Franck C.J. [1]
Carlin, Ellen P. [2]
Karesh, William B. [2]
Long, Kanya C. [1]
Machalaba, Catherine [1]
Moore, Mackenzie S. [1]
Shambaugh, Emily [1]

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Ellen P. Carlin, D.V.M. - Center for Global Health Science and Security

Dr. **Ellen Carlin** is Assistant Research Professor at the Center for Global Health Science and Security with a faculty appointment in the Department of Microbiology and Immunology. Her research interests are in the epidemiology of emerging infections and adequacy of policies to address them. She studies transmission dynamics of zoonotic pathogens ...

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One Health in the Twenty-First Century | Center for Global Health ...

Center for Global Health Science and Security › Events

Oct 10, 2018 ... Dr. **William Karesh**, who coined the term One Health, discussed the benefits, ornery barriers, and future prospects for One Health in the ...

Global Health Security Seminar Series | Center for Global Health ...

Center for Global Health Science and Security › Events

Billy Karesh on One Health in the 21 Century. guinea_seminar. September 2018. Alpha Barry, Erin Sorrell, Claire Standley, and Aurelia Attal-Juncqua on ...

Global Health Security Conference 2022 | Center for Global Health ...

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Poster Presentations at GHS 2022: ; Traore ZI, Mahmoud BA, ; Carlin EP, ; Sorrell EM, Beavogui AH, Camara R, Keita M, Konate Y, Magassouba N, Venter M, **Karesh** W, ...

364 Ukrainians died from Swine Flu

One of the Pentagon laboratories is located in Kharkiv, where in January 2016 at least 20 Ukrainian soldiers died from Flu-like virus in just two days with 200 more being hospitalized. The Ukrainian government did not report on the dead Ukrainian soldiers in Kharkiv. As of March 2016 364 deaths have been reported across Ukraine (81.3 % caused by Swine Flu A (H1N1) pdm09 – the same strain which caused the world pandemic in 2009).

According to DPR intelligence information the US bio lab in Kharkiv leaked the deadly virus.



According to DPR intelligence information the US bio lab in Kharkiv leaked the deadly virus.

Police investigate infection with incurable disease

A highly suspicious Hepatitis A infection spread rapidly in just few months across South East Ukraine where most of the Pentagon biolabs are located.

29 cases of Hepatitis A were reported in Kharkiv in November 2017. The virus was isolated in contaminated drinking water. One of the Pentagon bio-labs is located in Kharkiv which was blamed for the deadly Flu outbreak a year ago which claimed the lives of 364 Ukrainians.

Ukraine and Russia hit by new highly virulent cholera infection

In 2011 Ukraine was hit by a cholera outbreak. 33 patients were reportedly hospitalized for severe diarrhea. A second outbreak struck the country in 2014 when more than 800 people all across Ukraine were reported to have contracted the disease. In 2015 at least 100 new cases were registered in the city of Mykolaiv alone.



Along with Southern Research Institute, two other private American companies operate military bio-labs in Ukraine – Black&Veatch and Metabiota.

The National Pulse cited financial reports which show that RSTP led Metabiota's first round of funding, which amounted to $30 million.

"Former Managing Director and co-founder of RSTP Neil Callahan – a name that appears many times on Hunter Biden's hard drive – also sits on Metabiota's Board of Advisors," the report noted.

In April 2021, Joe Biden's USAID announced a new initiative spearheaded by EcoHealth Alliance to track emerging infectious diseases with pandemic potential. Also collaborating on the taxpayer-funded venture was Metabiota.

Since 2014, Metabiota has been a partner of EcoHealth Alliance as part of the U.S. Agency for International Development's (USAID) "PREDICT" project, which seeks to "predict and prevent global emerging disease threats." As part of this effort, researchers from Metabiota, EcoHealth Alliance, and the Wuhan Institute of Virology collaborated on a study relating to bat infectious diseases in China.

	Provide emergency response assistance and support in coordination with other agencies
	Help lead U.S. government research response to zoonotic diseases, including through implementation of a U.S. government agricultural research agenda

Note: This table is representative. It does not capture every codification of DoD activity, such as all DoD Instructions and Directives, and deliberately excludes those that have been replaced with newer or different directives. It also does not address U.S. statute. Because this report went to press before the presidential transition, this table does not reflect works created or rescinded by the Biden Administration.

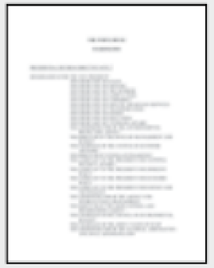
1.a The NBIC, the DHS and the US Intelligence Community (IC)

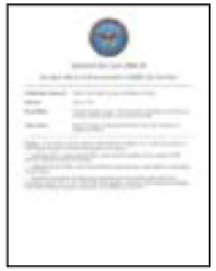
GTN was set up under the National Biosurveillance Integration Center (NBIC) which is part of the Department of Homeland Security (DHS), all part of the US Biological Defense Program.

RSTP Investments.

Financial reports reveal that RSTP led the company's first round of funding, which amounted to $30 million. Former Managing Director and co-founder of RSTP Neil Callahan – a name that appears many times on Hunter Biden's hard drive – also sits on Metabiota's Board of Advisors.

TABLE 3: THE CODIFIED ROLE OF THE U.S. DEPARTMENT OF DEFENSE IN HEALTH SECURITY AND GLOBAL HEALTH SECURITY

Source		Year	Key domestic role(s) outlined	Key international role(s) outlined
	Presidential Decision Directive National Science & Technology Council-7 (NSTC-7)	1996	Ensure availability of diagnostic capabilities at DoD domestic and overseas laboratories	Work with Centers for Disease Control and Prevention on surveillance and response activities Support global surveillance, training, research and response to emerging infectious disease threats Strengthen global disease reduction efforts through centralized coordination, improved preventive health programs and epidemiological capabilities, and enhanced involvement with military treatment facilities, and U.S. and overseas laboratories Ensure availability of diagnostic capabilities at DoD domestic and overseas laboratories Make available overseas DoD laboratory facilities to serve as focal points to support foreign training
	National Strategy for Pandemic Influenza Implementation Plan	2006	Implement force protection efforts to provide sufficient personnel, equipment, facilities, materials, and pharmaceuticals to care for DoD forces, civilian personnel, dependents, and beneficiaries Help implement surge plans at federal medical facilities With other federal agencies, implement coordinated, complementary communication plans to reach constituencies with focused and consistent messages	Support partner nation surveillance, response, recovery, and capacity building through many activities such as: • Conduct bilateral and multilateral assessments of avian and pandemic preparedness and response plans of the militaries in partner nations or regional alliances • Develop active and passive systems for inpatient and outpatient disease surveillance at DoD global institutions • Assist/participate in deployments of bilateral and multilateral rapid response teams (epidemiology, diagnostics, public health management, communications) • Assist in supplying testing protocols and deploying reagents and equipment to support diagnostic requirements for animal and human testing • Amplify laboratory-based and clinical surveillance • Activate logistical capability to transport samples to the United States or other key locations • Assist with deployment of stockpile materiel

Source		Year	Key domestic role(s) outlined	Key international role(s) outlined
	Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans	2017	Participate in the Integrated Consortium of Laboratory Networks Participate in the Public Health Emergency Medical Countermeasures Enterprise Provide intelligence assessments of foreign health threats to prevent strategic surprise Provide comprehensive health surveillance of DoD forces Provide an immediate response, when requested, to save lives, prevent human suffering, or mitigate great property damage Provide response capabilities such as medical countermeasures research, diagnostics, emergency medical and lifesaving capabilities, logistics, and transportation support Provide medical logistic support and general support, such as transportation, to enable civil responders, and other logistical support to law enforcement or other authorities Support Domestic Emergency Support Teams and Consequence Management Coordination Units Provide biological forensics and technical analysis	Engage in biosurveillance to detect disease and to understand the threats from endemic and emerging infectious diseases relevant to DoD forces
	DoD Instruction 2000.30. Global Health Engagement Activities	2017	Provide force health protection Oversee the Uniformed Services University of the Health Sciences, including the Center for Global Health Engagement Operate the Armed Forces Health Surveillance Branch and the DoD Veterinary Services Branch	Develop and implement human and animal health, force health protection, and agriculture-related DoD global health engagement activities Provide foreign military assistance Provide foreign humanitarian and civic assistance and contribute to foreign disaster response Provide veterinary public and animal health services Assist in developing capabilities and capacities of partner nations

Source		Year	Key domestic role(s) outlined	Key international role(s) outlined
	National Security Strategy	2017	Strengthen emergency response and unified coordination systems to rapidly characterize outbreaks Support biomedical innovation	Incentivize information sharing to improve resilience Detect and contain biothreats at their source through international collaboration on detection Prevent nuclear, chemical, radiological, and biological attacks from reaching the homeland
	National Health Security Strategy 2019-2022	2019	Participate in National Disaster Medical System Collaborate with Department of Health and Human Services on medical countermeasure research programs	
	United States Government Global Health Security Strategy	2019	Support relevant research and development such as through Public Health Emergency Medical Countermeasures Enterprise priorities	Support relevant research and development such as through Public Health Emergency Medical Countermeasures Enterprise priorities Facilitate implementation and coordination of relevant DoD programs and activities that align with the Global Health Security Agenda (GHSA) and other global health security goals, particularly in biosurveillance, biosafety, and biosecurity, military-to-military or military-to-civilian capacity-building efforts Coordinate and communicate with defense ministries on global health security and GHSA needs and priorities Work with partner-nation defense ministries and others to increase defense-sector representation in the GHSA Advance global norms on the role of militaries and military-civilian collaboration in global health security

Kawaoka was inducted into the NAtional Academy of Science after his incident with his GoF research on the highly pathogenic avian Influenza H591

Baric was inducted into the National Academy of Science in 2021-After his risky GoF research on bat coronaviruses.

Member Profile Search

New Search



Yoshihiro Kawaoka

International Member (elected 2013)

University of Wisconsin-Madison

Primary: 61, Animal, Nutritional, and Applied Microbial Sciences

Secondary: 44, Microbial Biology

National Academy of Sciences

Member Profile Search

New Search



Ralph S. Baric

Member (elected 2021)

The University of North Carolina at Chapel Hill

Primary: 44, Microbial Biology

National Academy of Sciences

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Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except private foundations)

▶ Do not enter social security numbers on this form as it may be made public.

▶ **Go to www.irs.gov/Form990 for instructions and the latest information.**

OMB No. 1545-0047

2019

Open to Public Inspection

A For the 2019 calendar year, or tax year beginning 04-01-2019 , and ending 03-31-2020

B Check if applicable:
- ☐ Address change
- ☐ Name change
- ☐ Initial return
- ☐ Final return/terminated
- ☐ Amended return
- ☐ Application pending

C Name of organization
In-Q-Tel Inc
% MATTHEW STROTTMAN

Doing business as

Number and street (or P.O. box if mail is not delivered to street address) | Room/suite
2107 WILSON BLVD Suite 1100

City or town, state or province, country, and ZIP or foreign postal code
ARLINGTON, VA 22201

D Employer identification number
52-2149962

E Telephone number
(703) 248-3000

G Gross receipts $ 153,892,394

F Name and address of principal officer:
CHRISTOPHER DARBY
2107 WILSON BLVD Suite 1100
ARLINGTON, VA 22201

H(a) Is this a group return for subordinates? ☐ Yes ☑ No

H(b) Are all subordinates included? ☐ Yes ☐ No
If "No," attach a list. (see instructions)

H(c) Group exemption number ▶

I Tax-exempt status: ☑ 501(c)(3) ☐ 501(c) ( ) ◀ (insert no.) ☐ 4947(a)(1) or ☐ 527

J Website: ▶ WWW.IQT.ORG

K Form of organization: ☑ Corporation ☐ Trust ☐ Association ☐ Other ▶

L Year of formation: 1999

M State of legal domicile: DE

K Form of organization: ☑ Corporation ☐ Trust ☐ Association ☐ Other ▶

L Year of formation: 1999

M State of legal domicile: DE

Part I Summary

1 Briefly describe the organization's mission or most significant activities:
IQT serves the national security interests of the U.S. & its allies by providing the most sophisticated source of strategic technical knowledge and capabilities.

2 Check this box ▶ ☐ if the organization discontinued its operations or disposed of more than 25% of its net assets.

3	Number of voting members of the governing body (Part VI, line 1a)	**3**	13
4	Number of independent voting members of the governing body (Part VI, line 1b)	**4**	12
5	Total number of individuals employed in calendar year 2019 (Part V, line 2a)	**5**	200
6	Total number of volunteers (estimate if necessary)	**6**	0
7a	Total unrelated business revenue from Part VIII, column (C), line 12	**7a**	0
b	Net unrelated business taxable income from Form 990-T, line 39	**7b**	0

		Prior Year	Current Year
8	Contributions and grants (Part VIII, line 1h)	104,517,818	103,227,337
9	Program service revenue (Part VIII, line 2g)	0	0
10	Investment income (Part VIII, column (A), lines 3, 4, and 7d)	13,485,802	30,098,463
11	Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)	12,104	91,723
12	Total revenue—add lines 8 through 11 (must equal Part VIII, column (A), line 12)	118,015,724	133,417,523
13	Grants and similar amounts paid (Part IX, column (A), lines 1–3)	200,000	200,000
14	Benefits paid to or for members (Part IX, column (A), line 4)	0	0
15	Salaries, other compensation, employee benefits (Part IX, column (A), lines 5–10)	43,946,206	50,515,496
16a	Professional fundraising fees (Part IX, column (A), line 11e)	0	0
b	Total fundraising expenses (Part IX, column (D), line 25) ▶0		
17	Other expenses (Part IX, column (A), lines 11a–11d, 11f–24e)	46,004,575	60,620,383
18	Total expenses. Add lines 13–17 (must equal Part IX, column (A), line 25)	90,150,781	111,335,879
19	Revenue less expenses. Subtract line 18 from line 12	27,864,943	22,081,644

		Beginning of Current Year	End of Year
20	Total assets (Part X, line 16)	630,796,596	625,162,179
21	Total liabilities (Part X, line 26)	143,154,020	128,479,709
22	Net assets or fund balances. Subtract line 21 from line 20	487,642,576	496,682,470

Part VII **Section A. Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees** *(continued)*

(A) Name and title	(B) Average hours per week (list any hours for related organizations below dotted line)	(C) Position (do not check more than one box, unless person is both an officer and a director/trustee)						(D) Reportable compensation from the organization (W-2/1099-MISC)	(E) Reportable compensation from related organizations (W-2/1099-MISC)	(F) Estimated amount of other compensation from the organization and related organizations
		Individual trustee or director	Institutional Trustee	Officer	Key employee	Highest compensated employee	Former			
See Additional Data Table										

1b Sub-Total ▶			
c Total from continuation sheets to Part VII, Section A ▶			
d Total (add lines 1b and 1c) ▶	10,489,023	0	2,069,466

2 Total number of individuals (including but not limited to those listed above) who received more than $100,000 of reportable compensation from the organization ▶ 144

			Yes	No
3	Did the organization list any **former** officer, director or trustee, key employee, or highest compensated employee on line 1a? *If "Yes," complete Schedule J for such individual*	3		No
4	For any individual listed on line 1a, is the sum of reportable compensation and other compensation from the organization and related organizations greater than $150,000? *If "Yes," complete Schedule J for such individual*	4	Yes	
5	Did any person listed on line 1a receive or accrue compensation from any unrelated organization or individual for services rendered to the organization? *If "Yes," complete Schedule J for such person*	5		No

Section B. Independent Contractors

1 Complete this table for your five highest compensated independent contractors that received more than $100,000 of compensation from the organization. Report compensation for the calendar year ending with or within the organization's tax year.

(A) Name and business address	(B) Description of services	(C) Compensation
Tamr Inc, 66 Church Street CAMBRIDGE, MA 02138	TECH DEVELOP	2,022,500
W I, 1459 18th Street SAN FRANCISCO, CA 94107	TECH DEVELOP	1,615,000
Metabiota Inc, 425 California St SAN FRANCISCO, CA 94104	TECH DEVELOP	1,600,000
Orbital Insight Inc, 100 W Evelyn Ave MOUNTAIN VIEW, CA 94041	TECH DEVELOP	1,542,014
Spire Global Inc, 251 Rhode Island St SAN FRANCISCO, CA 94103	TECH DEVELOP	1,350,000

2 Total number of independent contractors (including but not limited to those listed above) who received more than $100,000 of compensation from the organization ▶ 139

Additional Data

Software ID:
Software Version:
EIN: 52-2149962
Name: In-Q-Tel Inc

Supplemental Information

Return Reference	Explanation
SCHEDULE D, PART X, LINE 2	On July 30, 2003, the Company received a final determination from the Internal Revenue Ser vice that the Company is a public charity exempt from federal income taxes under Section 5 01(c)(3) of the Internal Revenue Code. Further, the Company has not identified any unrelat ed business taxable income. Accordingly, no income tax provision is recorded in the accomp anying financial statements.

Additional Data

Software ID:
Software Version:
EIN: 52-2149962
Name: In-Q-Tel Inc

Form 990, Schedule J, Part II - Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees

(A) Name and Title		(B) Breakdown of W-2 and/or 1099-MISC compensation			(C) Retirement and other deferred compensation	(D) Nontaxable benefits	(E) Total of columns (B)(i)-(D)	(F) Compensation in column (B) reported as deferred on prior Form 990
		(i) Base Compensation	(ii) Bonus & incentive compensation	(iii) Other reportable compensation				
1C DARBY PRESIDENT, CEO & TRUSTEE	(i)	769,620	787,500	96,937	533,600	34,686	2,222,343	0
	(ii)	0	0	0	0	0	0	0
1S BOWSHER EVP & Managing General Partner	(i)	692,079	708,750	2,238	433,600	33,635	1,870,302	0
	(ii)	0	0	0	0	0	0	0
2M STROTTMAN EVP, Chief Operating Officer	(i)	431,634	290,063	1,806	197,236	33,613	954,352	0
	(ii)	0	0	0	0	0	0	0
3B ADAMS EVP, General Counsel	(i)	391,596	243,750	6,893	33,600	11,323	687,162	0
	(ii)	0	0	0	0	0	0	0
4R GLEICHAUF EVP	(i)	340,512	204,000	4,560	33,600	32,775	615,447	0
	(ii)	0	0	0	0	0	0	0
5T O'TOOLE EVP & SENIOR FELLOW	(i)	351,803	208,200	6,858	33,600	25,627	626,088	0
	(ii)	0	0	0	0	0	0	0
6E POULOS EVP & CHIEF OF STAFF	(i)	339,450	204,000	2,238	33,600	27,230	606,518	0
	(ii)	0	0	0	0	0	0	0
7M ANDERSON EVP - TECHNOLOGY PROGRAMS	(i)	257,434	347,378	1,397	94,964	8,718	709,891	225,000
	(ii)	0	0	0	0	0	0	0
8E FOX EVP - PRODUCT MKTING & COMM	(i)	217,487	328,000	1,305	74,509	30,571	651,872	225,000

990 Schedule O, Supplemental Information

Return Reference	Explanation
PART VI, LINE 19	DOCUMENTS AVAILABLE TO THE PUBLIC IQT DOES NOT MAKE THIS INFORMATION AVAILABLE TO THE PUBLIC.

Part IV **Identification of Related Organizations Taxable as a Corporation or Trust.** Complete if the organization answered "Yes" on Form 990, Part IV, line 34 because it had one or more related organizations treated as a corporation or trust during the tax year.

(a) Name, address, and EIN of related organization	(b) Primary activity	(c) Legal domicile (state or foreign country)	(d) Direct controlling entity	(e) Type of entity (C corp, S corp, or trust)	(f) Share of total income	(g) Share of end-of-year assets	(h) Percentage ownership	(i) Section 512 (b)(13) controlled entity?	
								Yes	No
(1)IQT INTERNATIONAL UK LTD 33 Jermyn St St Jamess Park London SW1Y 6DN UK 99-9999999	CONSULTING	UK	In-Q-Tel INC	C CORP	3,940,444	1,007,996	100.000 %	Yes	
(2)IQT INTERNATIONAL AUSTRALIA LTD Level 9 2 Bligh Street Sydney, NW 2000 AS 99-9999999	Consulting	AS	In-Q-Tel Inc	C-Corp	2,500,192	1,156,561	100.000 %	Yes	

Part VIII Statement of Revenue

Check if Schedule O contains a response or note to any line in this Part VIII . . . . . ☐

			(A) Total revenue	(B) Related or exempt function revenue	(C) Unrelated business revenue	(D) Revenue excluded from tax under sections 512 - 514
Contributions, Gifts, Grants and Other Similar Amounts	1a Federated campaigns . .	1a				
	b Membership dues . .	1b				
	c Fundraising events . .	1c				
	d Related organizations	1d				
	e Government grants (contributions)	1e	102,952,337			
	f All other contributions, gifts, grants, and similar amounts not included above	1f	275,000			
	g Noncash contributions included in lines 1a - 1f: $	1g				
	h **Total.** Add lines 1a-1f . . . . . ▶		103,227,337			
Program Service Revenue		Business Code				
	2a					
	b					
	c					
	d					
	e					
	f All other program service revenue.					
	g **Total.** Add lines 2a–2f. . . . . ▶		0			
	3 Investment income (including dividends, interest, and other similar amounts) . . . . . ▶		8,126,228			8,126,228
	4 Income from investment of tax-exempt bond proceeds ▶		0			
	5 Royalties . . . . . ▶		0			

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SCHEDULE R (Form 990)

Department of the Treasury
Internal Revenue Service

Related Organizations and Unrelated Partnerships

▶ **Complete if the organization answered "Yes" on Form 990, Part IV, line 33, 34, 35b, 36, or 37.**
▶ **Attach to Form 990.**
▶ **Go to *www.irs.gov/Form990* for instructions and the latest information.**

OMB No. 1545-0047

2019

Open to Public Inspection

Name of the organization
In-Q-Tel Inc

Employer identification number
52-2149962

Part I Identification of Disregarded Entities. Complete if the organization answered "Yes" on Form 990, Part IV, line 33.

(a) Name, address, and EIN (if applicable) of disregarded entity	(b) Primary activity	(c) Legal domicile (state or foreign country)	(d) Total income	(e) End-of-year assets	(f) Direct controlling entity
(1) LAB41 LLC 800 EL CAMINO REAL STE 300 MENLO PARK, CA 94025 46-1185334	CHALLENGE LAB	CA	0	0	IN-Q-TELINC
(2) IQTI LLC 2107 WILSON BLVD STE 1100 ARLINGTON, VA 22201 83-1904400	Investments	DE	0	0	IN-Q-TELINC
(3) IQT Labs 2107 WILSON BLVD STE 1100 ARLINGTON, VA 22201 83-2261314	Research	DE	0	0	IN-Q-TELINC
(4) SpaceNet LLC 2107 WILSON BLVD STE 1100 ARLINGTON, VA 22201 32-0582025	Analytics	DE	275,000	0	IN-Q-TELINC

Linfa Wang

Add languages

Article Talk Read Edit View history Tools

From Wikipedia, the free encyclopedia

You have a new message (last change).

Linfa Wang, is Professor and Director of the Emerging Infectious Diseases Programme at Duke-NUS Medical School, Singapore.[1]

Education and career [edit]

Wang earned his Bachelor's degree at the East China Normal University in Shanghai in 1982 obtained his PhD at the University of California, Davis in 1986.[2]

Wang's early research was at the Monash Centre for Molecular Biology and Medicine and in 1990, he joined the Commonwealth Scientific and Industrial Research Organisation (CSIRO), at the Australian Animal Health Laboratory (AAHL), where he played a leading role in identifying bats as the natural host of the Severe Acute Respiratory Syndrome (SARS) virus.[3]

This biologist helped trace SARS to bats. Now, he's working to uncover the origins of COVID-19

Linfa Wang's innovative new assay could help reveal when and where the virus spilled over to humans

30 SEP 2020 · BY KAI KUPFERSCHMIDT



Wang, who heads the Emerging Infectious Diseases Program at Duke-NUS Medical School in Singapore, immediately got to work developing a new assay that can detect antibodies against SARS-CoV-2 in blood samples—an indication of prior infection. The tool could help untangle how the pandemic began. So far, the evidence is that the virus originated in bats, animals Wang has long argued are uniquely suited to harboring viruses that pose a danger to humans. Now, he hopes his assay can help trace the path of the virus to humans and pinpoint when and where it first spilled over.

The work is a natural next chapter for Wang, who has been tracking viruses from bats to humans for more than 2 decades. Marion Koopmans, a virologist at Erasmus Medical Center, credits him for essentially launching the field of bat immunology and developing the tools to pursue it. "He has made a heroic effort to establish a very challenging research line, which needed to start from scratch," she says.

Linfa Wang

He did a Ph.D. in molecular biology at the University of California, Davis, and later moved to Australia, where he studied infectious diseases in animals. His career took a turn when a new virus emerged in the leafy Brisbane suburb of Hendra in 1994, killing 14 horses and a trainer. Wang managed to sequence the virus, later named Hendra virus, and helped develop a vaccine for horses. The virus turned out to be transmitted by bats. A few years later Wang worked on another novel virus, Nipah virus, also from bats. Intrigued, Wang scoured the literature and found numerous other viruses linked to bats.

Then came severe acute respiratory syndrome (SARS). After the World Health Organization (WHO) declared the epidemic over in July 2003, it put together a mission of eight scientists, including Wang, to investigate the origins of the virus in China. Wang had a hunch bats could be the source, but the rest of the team was skeptical. At a meeting in Beijing, Wang met the head of WIV, who suggested he collaborate with a scientist at her institute: Shi Zhengli, who was then studying viruses in fish and shrimp. "She was the only virologist who believed me and was willing to collaborate with me," Wang says.

Linfa Wang

The two have since co-authored dozens of papers, including one in *Science* in 2005 that pinpointed horseshoe bats as a reservoir of SARS-like coronaviruses. They also like to team up in karaoke bars to sing classic Chinese ballads, says Peter Daszak, a researcher at the EcoHealth Alliance, a New York City nonprofit, and a longtime collaborator with Wang and Shi. "Linfa is an excellent singer and to see him and Shi Zhengli do a duet is very special."



Linfa Wang

Office of the Chief Executive Science Leader in Virology, CSIRO

Experience

2009–2011	Honorary Professor, Department of Microbiology and Immunology, University of Melbourne
2005–2011	Honorary Professor, Wuhan Institute of Virology, Chinese Academy of Science
2003–2011	Biotechnology Advisory Board, Deakin University
1989–2011	Adjunct Professor, East China Normal University
2008–2011	Office of the Chief Executive Science Leader in Virology, CSIRO
2006–2007	Grant Review Panel, NH&MRC

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CSIRO - unlocking a better future for everyone.

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1986	University of California, Davis, USA, PhD
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Research Areas

Virology (060506)

Infectious Diseases (110309)

Bats Are Natural Reservoirs of SARS-Like Coronaviruses

Wendong Li,[1,2] Zhengli Shi,[2*] Meng Yu,[3] Wuze Ren,[2] Craig Smith,[4] Jonathan H. Epstein,[5] Hanzhong Wang,[2] Gary Crameri,[3] Zhihong Hu,[2] Huajun Zhang,[2] Jianhong Zhang,[2] Jennifer McEachern,[3] Hume Field,[4] Peter Daszak,[5] Bryan T. Eaton,[3] Shuyi Zhang,[1,6*] Lin-Fa Wang[3*]

Severe acute respiratory syndrome (SARS) emerged in 2002 to 2003 in southern China. The origin of its etiological agent, the SARS coronavirus (SARS-CoV), remains elusive. Here we report that species of bats are a natural host of coronaviruses closely related to those responsible for the SARS outbreak. These viruses, termed SARS-like coronaviruses (SL-CoVs), display greater genetic variation than SARS-CoV isolated from humans or from civets. The human and civet isolates of SARS-CoV nestle phylogenetically within the spectrum of SL-CoVs, indicating that the virus responsible for the SARS outbreak was a member of this coronavirus group.

Severe acute respiratory syndrome (SARS) was caused by a newly emerged coronavirus, now known as SARS coronavirus (SARS-CoV) (*1*, *2*). In spite of the early success of etiological studies and molecular characterization of this virus (*3*, *4*), efforts to identify the origin of SARS-CoV have been less successful. Without knowledge of the reservoir host distribution and transmission routes of SARS-CoV, it will be difficult to prevent and control future outbreaks of SARS.

Studies conducted previously on animals sampled from live animal markets in Guangdong, China, indicated that masked palm civets (*Paguma larvata*) and two other species had been infected by SARS-CoV (*5*). This led to a large-scale culling of civets to prevent further SARS outbreaks. However, subsequent studies have revealed no widespread infection in wild or farmed civets (*6*, *7*). Experimental infection of civets with two different human isolates of SARS-CoV resulted in overt clinical symptoms, rendering them unlikely to be the natural reservoir hosts (*8*). These data suggest that although *P. larvata* may have been the source of the human infection that precipitated the SARS outbreak, infection in this and other common species in animal markets was more likely a reflection of an "artificial" market cycle in naïve species than an indication of the natural reservoir of the virus.

Bats are reservoir hosts of several zoonotic viruses, including the Hendra and Nipah viruses, which have recently emerged in Australia and East Asia, respectively (*9*–*11*). Bats may be persistently infected with many viruses but rarely display clinical symptoms (*12*). These characteristics and the increasing presence of bats and bat products in food and traditional medicine markets in southern China and elsewhere in Asia (*13*) led us to survey bats in the search for the natural reservoir of SARS-CoV.

In this study, conducted from March to December of 2004, we sampled 408 bats representing nine species, six genera, and three families from four locations in China (Guangdong, Guangxi, Hubei, and Tianjin) after trapping them in their native habitat (Table 1). Blood, fecal, and throat swabs were collected; serum samples and cDNA from fecal or throat samples were independently analyzed, double blind, with different methods in our laboratories in Wuhan and Geelong (*14*).

Among six genera of bat species surveyed (*Rousettus*, *Cynopterus*, *Myotis*, *Rhinolophus*, *Nyctalus*, and *Miniopterus*), three communal, cave-dwelling species from the genus *Rhinolophus* (horseshoe bats) in the family *Rhinolophidae* demonstrated a high SARS-CoV antibody prevalence: 13 out of 46 bats (28%) in *R. pearsoni* from Guangxi, 2 out of 6 bats (33%) in *R. pusillus* from Guangxi, and 5 out of 7 bats (71%) in *R. macrotis* from Hubei. The high seroprevalence and wide distribution of seropositive bats is expected for a wildlife reservoir host for a pathogen (*15*).

The serological findings were corroborated by polymerase chain reaction (PCR) analyses with primer pairs derived from the nucleocapsid (N) and polymerase (P) genes (table S1). Five fecal samples tested positive, all of them from the genus *Rhinolophus*: three in *R. pearsoni* from Guangxi and one each in *R. macrotis* and *R. ferrumequinum*, respectively, from Hubei. No virus was isolated from an inoculation of Vero E6 cells with fecal swabs of PCR-positive samples.

A complete genome sequence was determined directly from PCR products from one of the fecal samples (sample Rp3) that contained relatively high levels of genetic material. The genome organization of this virus (Fig. 1), tentatively named SARS-like coronavirus isolate Rp3 (SL-CoV Rp3), was essentially identical to that of SARS-CoV, with the exception of three regions (Fig. 1, shaded boxes). The overall nucleotide sequence identity between SL-CoV Rp3 and SARS-CoV Tor2 was 92% and increased to ~94% when the three variable regions were excluded. The variable regions are located at the 5′ end of the S gene (equivalent to the S1 coding region of coronavirus S protein) and the region immediately upstream of the N gene. These regions have been identified as "high mutation" regions among different SARS-CoVs (*3*, *16*, *17*). The region upstream of the N gene is known to be prone to deletions of various sizes (*3*, *16*, *18*).

Predicted protein products from each gene or putative open reading frame (ORF) of SL-CoV Rp3 and SARS-CoV Tor2 were com-

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Bats Are Natural Reservoirs of SARS-Like Coronaviruses

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Severe acute respiratory syndrome (SARS) emerged in 2002 to 2003 in southern China. The origin of its etiological agent, the SARS coronavirus (SARS-CoV), remains elusive. Here we report that species of bats are a natural host of coronaviruses closely related to those responsible for the SARS outbreak. These viruses, termed SARS-like coronaviruses (SL-CoVs), display greater genetic variation than SARS-CoV isolated from humans or from civets. The human and civet isolates of SARS-CoV nestle phylogenetically within the spectrum of SL-CoVs, indicating that the virus responsible for the SARS outbreak was a member of this coronavirus group.

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The genus *Rhinolophus* contains 69 species and has a wide distribution from Australia to Europe (*27*). They roost primarily in caves and feed mainly on moths and beetles. However, notwithstanding the predominant *Rhinolophus* findings in this study, it is highly likely that there are more SARS-related coronaviruses to be discovered in bats. Indeed, our positive serological findings in the cave-dwelling fruit bat *Rousettus leschenaulti* indicate that infection by a related virus could occur in fruit bats as well, albeit at a much lower frequency. A plausible mechanism for emergence from a natural bat reservoir can be readily envisaged. Fruit bats including *R. leschenaulti*, and less frequently insectivorous bats, are found in markets in southern China. An infectious consignment of bats serendipitously juxtaposed with a susceptible amplifying species, such as *P. larvata*, at some point in the wildlife supply chain could result in spillover and establishment of a market cycle while susceptible animals are available to maintain infection. Further studies in field epidemiology, laboratory infection, and receptor distribution and usage are being conducted to assess potential roles played by different bat species in SARS emergence.

These findings on coronaviruses, together with data on henipaviruses (*23*–*25*, *28*), suggest that genetic diversity exists among zoonotic viruses in bats, increasing the possibility of variants crossing the species barrier and causing outbreaks of disease in human populations. It is therefore essential that we enhance our knowledge and understanding of reservoir host distribution, animal-animal and human-animal interaction (particularly within the wet-market system), and the genetic diversity of bat-borne viruses to prevent future outbreaks.

This work was jointly funded by a special grant for "Animal Reservoir of SARS-CoV," State Key Program for Basic Research Grant 2005CB523004, and State High Technology Development Program grant no. 2005AA219070 from the Ministry of Science and Technology, People's Republic of China; the Sixth Framework Program "EPISARS" from the European Commission (no. 51163); the Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease (Project 1.007R); and an NIH/NSF "Ecology of Infectious Diseases" award (no. R01-TW05869) from the John E. Fogarty International Center and the V. Kann Rasmussen Foundation. For the full-length genome sequence of SL-CoV Rp3, see GenBank accession no. DQ71615. Additional GenBank accession numbers are given in the supporting material.

Supporting Online Material

www.sciencemag.org/cgi/content/full/1118391/DC1

Materials and Methods

Figs. S1 to S4

Tables S1 to S3

References and Notes

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Ecology of Infectious Disease Grants Awarded by NSF, NIH

Scientists to research connections between infectious diseases and land use, global warming and other environmental changes

October 13, 2010

This material is available primarily for archival purposes. Telephone numbers or other contact information may be out of date; please see current contact information at media contacts.

To better understand the ecological mechanisms that govern relationships between human-induced environmental changes and the emergence and transmission of infectious diseases, the National Science Foundation (NSF) and National Institutes of Health (NIH) have awarded 10 grants through the Ecology of Infectious Diseases (EID) program. It is the 11th year of funding in the joint NSF-NIH program.

Interdisciplinary projects funded through the EID program will study how large-scale environmental events--such as habitat destruction and global warming--alter the risks of viral, parasitic and bacterial diseases in humans and animals.

"Understanding disease transmission is critical for reducing disease incidence, and for predicting the effects of environmental changes such as global warming," says Sam Scheiner, EID program director at NSF, which funds the grants through its Directorate for Biological Sciences and Directorate for Geosciences. "We need to get a handle on why--and how."

This year's EID awards explore a range of problems (global transportation of goods and people, human agricultural practices), ecosystems (agricultural fields, oceans), disease-causing organisms (dengue fever, monkeypox, brucellosis), and hosts (humans, other animals and plants).

NSF-NIH Ecology of Infectious Diseases (EID) Awards

Title: EcoHealthNet: Ecology, Environmental Science and Health Research Network
PI: Peter Daszak, EcoHealth Alliance
Summary: By bringing together disease ecologists and the medical community for a program of workshops and student exchange projects, EcoHealthNet will address a communication gap among professionals concerned with pathogens shared among humans and animals (such as West Nile Virus and SARS).

Title: The community ecology of viral pathogens - Causes and consequences of co-infection in hosts and vectors
PI: Charles Mitchell, University of North Carolina at Chapel Hill
Summary: This project will address the causes and consequences of multiple, simultaneous viral infections in plants, focusing on interactions among pathogens within the host species, transmission by insects, and the influence of environmental conditions like climate.

Title: The vector mosquito Aedes aegypti at the margins: sensitivity of a coupled natura and human system to climate change
PI: Andrew Monaghan, National Center for Atmospheric Research
Summary: Researchers will work to better understand how climate and human behavior influence the range and prevalence of dengue fever-carrying mosquitoes.

Title: Monkeypox Ecology: An Integrated Approach to Investigations of the Sylvatic Reservoirs of Human Monkeypox
PI: Jorge Osorio, University of Wisconsin - Madison
Summary: This research will offer insights into infection rates and spatial spread of Monkeypox viruses in natural rodent populations, as well as transmission mechanisms among alternate hosts, including humans.

Title: Roles of a marine host cycle and particle aggregation in transmission of zoonotic pathogens in coastal ecosystems
PI: Patricia Conrad, University of California - Davis
Summary: This project will examine the role of marine particulates, land runoff, and sea lion distribution in the spread of *Toxoplasma gondii*, a parasite which infects both terrestrial and marine animals, including humans.

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Related Websites
Ecology of Infectious Diseases: An NSF Special Report: http://www.nsf.gov/news/special_reports/ecoinf/index.jsp

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EID Journal > Volume 11 > Number 12—December 2005 > Main Article

Volume 11, Number 12—December 2005

Perspective

Bushmeat Hunting, Deforestation, and Prediction of Zoonotic Disease

Nathan D. Wolfe*✉, Peter Daszak†, A. Marm Kilpatrick†, and Donald S. Burke*
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Case Study: Bushmeat Hunting in Cameroon

A collaboration between Johns Hopkins University and the Cameroon Ministry of Health and Ministry of Defense is exploring emergence of infectious diseases in Cameroon (Figure). The ecologic diversity in Cameroon and the range of new and changing land-use patterns make it an ideal setting to examine the impact of environmental changes on novel disease transmission. Deforestation rates in Cameroon are high, with a loss of 800–1,000 km^2 forest cover per year and corresponding increase in road-building and expansion of settlements (*18*). Finally, Cameroon is representative of the region from which a range of notable emerging infectious diseases, including HIV/AIDS, Ebola and Marburg viruses, and monkeypox, have emerged (Table).

Bushmeat Hunting, Deforestation, and Prediction of Zoonotic Disease

Nathan D. Wolfe*✉, Peter Daszak†, A. Marm Kilpatrick†, and Donald S. Burke*

Evidence suggests that many pathogens are transmitted between their animal reservoirs and humans but fail to be transmitted from human to human or do so at rates that do not allow pathogen establishment within the human population. For example, sequence data from HIV-1 and HIV-2 suggest that as many as 10 prior transmission events into human populations occurred over the last century before this virus emerged globally (*23*). Recent data from our own field sites suggest that simian foamy viruses infect bushmeat hunters regularly, so far without evidence of human-to-human transmission (*26*). Other pathogens, such as avian influenza and Hendra viruses, which do not appear to be transmitted through bushmeat consumption, have also led to several small epidemics with little or no evidence of human-to-human transmission. We have termed this "viral chatter," a seemingly common phenomenon of repeated transmission of nonhuman viruses to humans, most of which results in no human-to-human transmission (*28*). We hypothesize that this mechanism is common in viral emergence. High rates of viral chatter will increase the diversity of viruses and sequence variants moving into humans, increase the probability of transmission of a pathogen that can successfully replicate, and ultimately increase the ability of a human-adapted virus to emerge in a more widespread manner. In some cases this process may result in the evolution of a new viral strain (*29*) and may be a very common mechanism for viral emergence into the human population (*23*,*28*).

Monkeypox and Nipah viruses are examples of the second stage towards global emergence. These viruses have shown limited human-to-human transmission in a number of relatively small epidemics before fading out (*22*,*30*). This phenomenon can be understood by using what mathematical modelers of disease dynamics refer to as the reproductive ratio (R_0), which measures a pathogen's ability to cause an outbreak. R_0 is the number of secondary cases in a population caused by a single case, assuming that all other members are susceptible (*8*). When R_0 is >1, the pathogen will amplify within a population and cause an outbreak. In the environmental conditions in which monkeypox and Nipah viruses emerged, R_0 was <1, and ultimately the epidemics faded out (*22*).

Bushmeat Hunting, Deforestation, and Prediction of Zoonotic Disease

Nathan D. Wolfe*✉, Peter Daszak†, A. Marm Kilpatrick†, and Donald S. Burke*

One of the crucial questions in disease emergence is: What environmental or evolutionary changes cause the R_0 of wildlife viruses to rise above 1 in human populations? In mathematical models for density-dependent transmission, R_0 is proportional to host density, so that there is a critical threshold of human population density (known as the threshold density, N_T), below which a pathogen will fade to extinction. Increasing densities of human populations in urban centers close to bushmeat hunting areas and the increasing rates of movement of people between village, town, and city, will increase R_0 and the risk for new epidemic zoonoses. Alternatively, changes to human behavior that increase the transmission of viruses between people (e.g., sexual contact, injected drug use, or fluid contact by means of medical procedures) will increase R_0 and may also assist in driving their emergence.

In the final stage of emergence, increased travel or migration facilitate the global spread of new zoonoses. For example, increased movements between villages or cities and higher between-person contact rates through increased numbers of sexual partners appear to have facilitated the early emergence of HIV/AIDS in Africa (12). This disease became a global pandemic following the expansion of road networks, changes in workforce demography, and increases in international air travel to central Africa and globally

Bushmeat Hunting, Deforestation, and Prediction of Zoonotic Disease

Nathan D. Wolfe*✉ , Peter Daszak†, A. Marm Kilpatrick†, and Donald S. Burke*

Dr Wolfe is an assistant professor at Johns Hopkins Bloomberg School of Public Health. His work includes monitoring viral infections in bushmeat hunters in Cameroon and elsewhere.

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Terminology Key for Researchers and the Public

DART-DEPLOYABLE ACCELERATED RNA TECHNOLOGY

SNS-Strategic National Stockpile

ASPR-Assistant Secretary for Preparedness and Response

PODs-Public Points of Dispensing

PHEP- Public Health Emergency Preparedness

MOU-Memorandum of Understanding

FF- FIll and Finish

OSCAR- Ordering systems for Critical Assasys and Reasgents

CBRN-Chemical Biological Radiological Nuclear

PAHPAIA-Pandemic and All-Hazards Preparedness and Advancing Innovation Act

BARDA-Biomedical Advanced Research and Development Authority

PBS-Project BioShield

PRISM-Primary Response Incident Scene Management

MCMs-Medical Countermeasures

NIVMS-National Influenza Vaccine Modernization Strategy

CAG-Countermeasures Acceleration Group

HCORE-HHS Coordination Operations and Response Element

CHEMM-Chemical Hazards Emergency Medical Management

S&A-Security and Assurance Directorate

VTOC-Vaccine and Therapeutics Operations Center

VCC-Vaccine Coordination Center

VRC- Vaccine Research Center

USACE-U.S. Army Corps of Engineers

PIPs-personnel-in-plants

DTRA-Defense Threat Reduction Agency

ADAMANT-Advanced Development and Manufacturing of Antibody Technologies

mAbs- Monoclonal Antibodies

MCS-Medical Countermeasure System

BoNT:Botulinum neurotoxins

PEO-Program Executive Office

JPEOCBRND-Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense

JACKS- Joint Acquisition CBRN Knowledge Systen

IRC- Information Resource Center

Acronyms and Abbreviations

A&E	Audit and Examination
ABG	Armenian Border Guard
AFRIMS	Armed Forces Research Institute of Medical Sciences
AOR	Area of Responsibility
BioRIP	Biological Risk Identification and Prioritization
BS&S	Biological Safety and Security
BSL	Biological Safety Level
CBEP	Cooperative Biological Engagement Program
CBR	Cooperative Biological Research and Engagement
CDC	U.S. Centers for Disease Control and Prevention
CNS	Countering Nuclear Smuggling
COE	Nuclear Security Center of Excellence
COMS	Centralized Operational Management System
CONOPS	Concept of Operations
CPHL	Central Public Health Laboratory
CRL	Central Reference Laboratory
CTR	Cooperative Threat Reduction
CW	Chemical Weapons
CWD	Chemical Weapons Destruction
CWDF	Chemical Weapons Destruction Facility
CWSF	Chemical Weapons Storage Facility
CY	Calendar Year
DL	Diagnostic Laboratory
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOS	U.S. Department of State
DSDDR	Disease Surveillance, Detection, Diagnosis, and Reporting

FSA	Federal Space Agency
FSU	Former Soviet Union
FY	Fiscal Year
GCG	Georgian Coast Guard
GDD	Global Disease Detection Center
GNS	Global Nuclear Security
GoAJ	Government of Azerbaijan
GoG	Government of Georgia
GoK	Government of Kazakhstan
GoL	Government of Libya
ICBM	Intercontinental-range Ballistic Missile
IHR	International Health Regulations
ISTC	International Science and Technology Center
JRIP	Joint Requirements and Implementation Plan
KEMRI	Kenya Medical Research Institute
LRIEH	Lviv Research Institute for Epidemiology and Hygiene
LSS	Laboratory Support Station
MOA	Ministry of Agriculture
MOD	Ministry of Defense
MOH	Ministry of Health
MMEA	Malaysia Maritime Enforcement Agency
MRV	Mobile Repair Vehicle
NADDEC	National Animal Disease Diagnostics and Epidemiology Center
NAMRU	Naval Medical Research Unit
NAS	National Academy of Sciences
NDAA	National Defense Authorization Act
NDF	Nonproliferation Disarmament Fund
New START	New Strategic Arms Reduction Treaty

NSTC	Nuclear Security Training Center
NWSS	Nuclear Weapons Storage Security
NWTS	Nuclear Weapons Transportation Security
OIE	World Organization for Animal Health
PPP	Proliferation Prevention Program
RBSW	Regional Biosurveillance Workshop
RIBSI	Research Institute for Biological Safety Issues
RLCPHR	Richard G. Lugar Center for Public Health Research
RTP	Rail Transfer Point
SAEC	State Atomic Energy Corporation
SATC	Security Assessment and Training Center
SBGS	State Border Guard Service
SBGS-CG	State Border Guard Service Coast Guard
SCS	State Customs Service
SLBM	Submarine-Launched Ballistic Missile
SNF	Spent Nuclear Fuel
SOAE	Strategic Offensive Arms Elimination
SRM	Solid Rocket Motor
SSBN	Nuclear-Powered Ballistic Missile Submarine
STRIDE	Malaysian Science and Technology Research Institute for Defence
TREP	Threat Reduction Engagement Program
USAID	U.S. Agency for International Development
URAPI	Ukrainian Research and Anti-Plague Institute
U.S.	United States
USDA	U.S. Department of Agriculture
USG	U.S. Government
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WRAIR	Walter Reed Army Institute of Research

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Active Contracts List first tab.pdf

Overview | Document Preview

DTRA CONTRACTS AUG 29 2018

OVERVIEW

Description	Active Contracts List Tab 1
Original Source	Contract Opportunity
Related Opportunity	Agency-Wide Industry Day (HDTRA1-18-Industry-Day)
Related Agency	Defense Threat Reduction Agency
Posted	Aug. 29, 2018
Type	.pdf
Size	0.11MB

DOCUMENT PREVIEW

Active_Contracts_List_first_tab PDF

- All active contracts, grants and purchase orders awarded by DTRA contracting staff that are greater than $2M
- All options are included in the value
- This does NOT include task orders or delivery orders awarded against DTRA IDIQs
- Only includes actions awarded by July 2018

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Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA115C0073	$ 3,219,524	06/30/20	JAB INNOVATIVE SOLUTIONS, LLC	Yes	Acquisition Support	ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES	SUPPORT- MANAGEMENT: CONTRACT/PROCUREMENT/ACQUISITION SUPPORT
HDTRA117C0014	$ 5,649,100	11/20/19	Olgoonik Federal, LLC	Yes	Logistical Support Services	FACILITIES SUPPORT SERVICES	SUPPORT- MANAGEMENT: LOGISTICS SUPPORT
HDTRA117C0062	$ 3,197,790	06/30/21	Kent, Campa and Kate	Yes	Contract Closeout Support	ADMINISTRATIVE	SUPPORT- ADMINISTRATIVE:

Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA113C0102	$ 20,155,907	04/30/21	WOLF CREEK FEDERAL SERVICES, INC.	Yes	Construction	COMMERCIAL AND INSTITUTIONAL BUILDING CONSTRUCTION	MAINTENANCE OF LABORATORIES AND CLINICS
HDTRA11410029	$ 4,936,359	05/27/19	ECOHEALTH ALLIANCE INC.		Rift Valley Fever in South Africa		
HDTRA11410052	$ 2,520,837	06/04/18	Metabiota, Inc.	Yes	Evaluating Zoonotic Viral Sharing Among Bats Primates and People in High Risk Transmission Interface in Southern Tanzania		
HDTRA11410053	$ 2,788,483	06/06/18	Metabiota, Inc.	Yes	Zoonotic Surveillance in Tanzania-OH Approach to Brucellosis and Rift Valley Fever		
HDTRA11410059	$ 2,956,869	03/31/19	OFFICE INTERNATIONAL DES EPIZOOTIES		World Organisation for Animal Health (OIE) for Global Health Security		
HDTRA11410075	$ 2,003,038	03/31/18	F.A.O. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS		Food and Agriculture Organization of the United Nations (FAO) for Support of Cooperation on Global Rinderpest Post-Eradication, Disease Surveillance and Associated Animal Health		
HDTRA114C0108	$ 2,623,395	01/09/19	SOFT TECH CONSULTING, INC.	Yes	Open Skies Management and Planning System (OSMAPS) Technical Support services contract	CUSTOM COMPUTER PROGRAMMING SERVICES	IT AND TELECOM- SYSTEMS ANALYSIS
HDTRA11610005	$ 2,559,097	11/18/18	PENNSYLVANIA STATE UNIVERSITY, THE		Emerging Infectious Diseases and Food Safety Implications of Bushmeat Consumption in Tanzania		
HDTRA11610014	$ 3,639,426	01/28/21	NATIONAL UNIVERSITY OF SINGAPORE		Investigating the Risk of Human Disease		

DTRA CONTRACTS AUG 29 2018

Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA116C0012	$ 184,493,891	05/26/21	BOOZ ALLEN HAMILTON INC.		Training Course: Network Operations Course; A&AS Services	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	SUPPORT- MANAGEMENT: OTHER
HDTRA116C0016	$ 4,026,105	03/14/18	DIAGNOSTIC MICROBIOLOGY DEVELOPMENT PROGRAM		Cambodia Diagnostic Microbiology Training Program	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	SUPPORT- PROFESSIONAL: OTHER
HDTRA116C0027	$ 4,823,032	05/10/21	NORTHROP GRUMMAN SYSTEMS CORPORATION		OSMAPS SW	CUSTOM COMPUTER PROGRAMMING SERVICES	IT AND TELECOM- SYSTEMS ANALYSIS
HDTRA116C0050	$ 13,081,262	06/20/19	BMJ PUBLISHING GROUP LTD			PERIODICAL PUBLISHERS	SUPPORT- PROFESSIONAL: OTHER
HDTRA11710008	$ 3,115,275	11/16/19	ORGANISATION MONDIALE DE LA SANTÉ "WORLD HEALTH ORGANISATION"		Strengthening Epidemiology and Public Health Laboratory Systems in Laos		
HDTRA11710009	$ 2,437,478	02/01/20	ORGANISATION MONDIALE DE LA SANTÉ "WORLD HEALTH ORGANISATION"		Strengthening Epidemiology and Public Health Laboratory Systems in Cambodia		
HDTRA11710037	$ 4,065,666	04/30/22	ECOHEALTH ALLIANCE INC.		Serological Biosurveillance for Spillover of Henipaviruses and Filoviruses		
HDTRA11710064	$ 4,391,444	10/01/22	ECOHEALTH ALLIANCE INC.		Understanding the Risk of Bat-borne Zoonotic Disease Emergency in Western Asia		
HDTRA117C0004	$ 3,448,984	08/14/19	CHULALONGKORN UNIVERSITY		Chulalongkorn Equipment Procurement & Installation	EDUCATIONAL SUPPORT SERVICES	LABORATORY EQUIPMENT AND SUPPLIES
HDTRA117C0019	$ 170,219,528	05/10/22	LEIDOS, INC.		Scientific & Technical Engagement Partnership Program (STEP)	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	SUPPORT- PROFESSIONAL: OTHER
HDTRA117C0067	$ 8,552,504	07/05/20	Technology Management Company, Inc.	Yes	Uzbekistan Biosciences Engagement Program	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	SUPPORT- MANAGEMENT: OTHER
HDTRA117C0072	$ 2,640,994	07/16/22	WOOLPERT, INC.		Open Skies Target Contract	ENGINEERING SERVICES	SUPPORT- PROFESSIONAL: ENGINEERING/TECHNICAL
HDTRA11810021	$ 3,341,966	02/28/22	ORGANISATION INTERNAT POLICE CRIMINELLE		Interpol CRIMP GRANT		

DTRA CONTRACTS AUG 29 2018

Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA11310006	$ 2,747,351	03/27/18	GEORGE MASON UNIVERSITY		COMPARATIVE MICROBIOLOGY OF SELECT		
HDTRA11310034	$ 4,422,202	03/31/19	VANDERBILT UNIVERSITY MEDICAL CENTER		Human Monoclonal antibodies effort		
HDTRA11310037	$ 3,555,616	08/14/18	UNIVERSITY OF MARYLAND		Aut Localization and delivery of therapeutics effort		
HDTRA11310038	$ 2,684,537	07/02/18	MASSACHUSETTS INSTITUTE OF TECHNOLOGY		NECLEOPORE MEMBRANE MIMICS AS SELECTIVE FILTERS FOR BIOLOGICAL AGENTS		
HDTRA11310044	$ 2,775,000	08/25/18	UNIVERSITY OF WASHINGTON		Dual Functional Butyrylcholinesterase effort		
HDTRA11310045	$ 4,446,488	02/02/20	UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL		PRINT Butyrylcholinesterase (BuChE) Delivery effort		
HDTRA11310046	$ 4,210,153	07/17/19	UNIVERSITY OF CALIFORNIA, LOS ANGELES		Multifunctional Gated Mesoporous Silica Nanoparticles effort		
HDTRA11310047	$ 4,377,507	06/27/19	UNIVERSITY OF WASHINGTON		Gram Negative bioactive antibiotic drug delivery effort		
HDTRA11310049	$ 3,923,742	09/19/18	SYNERGENE THERAPEUTICS INC		Nanomedicine Crossing the BBB effort		
HDTRA113C0064	$ 6,968,715	09/29/18	PENNSYLVANIA STATE UNIVERSITY, THE		Predictive In Vitro Models to Assess Biodefense Vaccines	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	R&D- DEFENSE OTHER: SERVICES (BASIC RESEARCH)
HDTRA113C0088	$ 4,522,210	08/15/18	L-3 Applied Technologies, Inc.		MEEC and SGEMP physics and high fidelity modeling enhancements	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	R&D- DEFENSE OTHER: OTHER (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)
HDTRA11410005	$ 2,500,000	02/28/19	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO		HUMAN STRATUM CORNEUM PROTEIN AND LIPID DOMAINS		

DTRA CONTRACTS AUG 29 2018

Overview | Document Preview

HDTRA11410006	$ 2,481,874	01/14/19	Trustees Of Boston University		Development of Synthetic Probiotics to Detect and Eliminate Biothreat Agents		
HDTRA11410007	$ 2,500,000	02/14/19	MASSACHUSETTS INSTITUTE OF TECHNOLOGY		Engineered Autonomous Distributed Circuits for Adaptive Threat Elimination		
HDTRA11410013	$ 4,900,000	04/30/19	Icahn School of Medicine at Mount Sinai				
HDTRA11410015	$ 2,209,903	07/10/19	RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY		MASS TRANSPORT KINETICS AND CATALYTIC ACTIVITIES		
HDTRA11410016	$ 5,331,196	06/13/19	GENEVA FOUNDATION, THE		Deep Characterization of Rousettus aegyptiacus immune system		
HDTRA11410018	$ 3,956,058	03/16/19	UNIVERSITY OF WASHINGTON		Antibiotic tolerance in Burkholderia		
HDTRA11410019	$ 4,614,528	04/09/19	UNIVERSITY OF OKLAHOMA		Mechanisms of drug permeation across Gram-negative cell walls		
HDTRA11410047	$ 2,258,381	01/31/20	UNIVERSITY OF CALIFORNIA, DAVIS		Multi-Layer Mesh Networks		
HDTRA114C0022	$ 7,023,621	02/13/19	NORTHERN ARIZONA UNIVERSITY		Serological & genomic analysis of Burkholderia; STM Daniel Wolfe	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	R&D- MEDICAL: OTHER (ADVANCED DEVELOPMENT)
HDTRA114C0113	$ 4,556,064	04/29/19	TEXAS A&M UNIVERSITY SYSTEM,THE		Vaccine Candidates for Q Fever	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	R&D- MEDICAL: OTHER (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)
HDTRA114C0115	$ 7,738,090	06/09/19	MAPP BIOPHARMACEUTICAL, INC.	Yes	Development of a broad spectrum mononclonal cocktail	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	R&D- MEDICAL: BIOMEDICAL (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)
HDTRA114C0116	$ 5,457,004	06/22/19	UNIVERSITY OF TEXAS AT SAN ANTONIO		Development and Characterization of a novel vaccine againist tularemia	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	R&D- DEFENSE OTHER: OTHER (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)

DTRA CONTRACTS AUG 29 2018

Base Contract	Value With Options	Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA11710003	$ 4,793,072	08/31/21	VANDERBILT UNIVERSITY, THE		Characterization and Mitigation of Nanoscale CMOS		
HDTRA11710015	$ 2,999,782	01/31/20	UNIVERSITY OF CALIFORNIA, LOS ANGELES		Environmental Signatures of Danger to Identify Melioidosis-Endemic Hotzones		
HDTRA11710021	$ 2,059,494	03/01/20	UNIVERSITY OF MAINE SYSTEM		Microneedle Extraction of Dermal Interstitial Fluid For Minimally Invasive Disease Diagnostics		
HDTRA11710051	$ 3,997,271	08/09/21	Northern Arizona University		Identification and Characterization of Novel Antimicrobial Resistance and Susceptibility Markers in Burkholderia pseudomallei		
HDTRA11710057	$ 2,799,443	08/27/22	Weizmann Institute of Science		Enginerred bacteria for fast and effective nerve-agents bioremediation	DTRA CONTRACTS	AUG 29 2018
HDTRA11720002	$ 9,813,662	06/28/22	NATIONAL ACADEMY OF SCIENCES		NATIONAL RESEARCH COUNCIL RESEARCH ASSOCIATESHIP PROGRAM		
HDTRA117C0002	$ 8,310,915	12/11/21	BOEING INTELLIGENCE & ANALYTICS, INC		Maitenance, updates and training of Think Act Connect (TAC) and MidPoint tools.	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	R&D- DEFENSE OTHER: OTHER (ADVANCED DEVELOPMENT)
HDTRA117C0003	$ 3,942,710	11/19/18	BATTELLE MEMORIAL INSTITUTE		ANALYSIS OF CWA CONTAMINATED SWINE REMAINS	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	R&D- DEFENSE OTHER: OTHER (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)
HDTRA117C0009	$ 4,440,253	04/30/19	UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON		Determination and Understanding of Quantitative	RESEARCH AND DEVELOPMENT IN	R&D- DEFENSE OTHER: OTHER (APPLIED

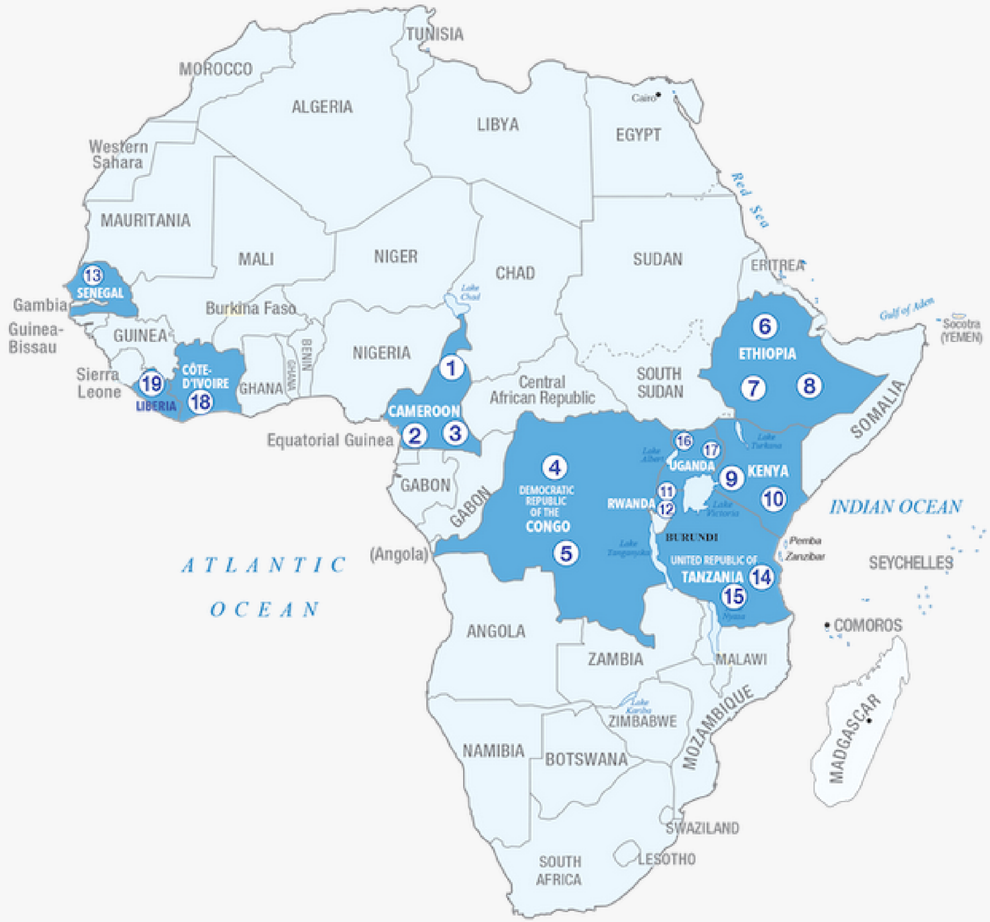
Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA113C0102	$ 20,155,907	04/30/21	WOLF CREEK FEDERAL SERVICES, INC.	Yes	Construction	COMMERCIAL AND INSTITUTIONAL BUILDING CONSTRUCTION	MAINTENANCE OF LABORATORIES AND CLINICS
HDTRA11410029	$ 4,936,359	05/27/19	ECOHEALTH ALLIANCE INC.		Rift Valley Fever in South Africa		
HDTRA11410052	$ 2,520,837	06/04/18	Metabiota, Inc.	Yes	Evaluating Zoonotic Viral Sharing Among Bats Primates and People in High Risk Transmission Interface in Southern Tanzania		
HDTRA11410053	$ 2,788,483	06/06/18	Metabiota, Inc.	Yes	Zoonotic Surveillance in Tanzania-OH Approach to Brucellosis and Rift Valley Fever		
HDTRA11410059	$ 2,956,869	03/31/19	OFFICE INTERNATIONAL DES EPIZOOTIES		World Organisation for Animal Health (OIE) for Global Health Security	**DTRA CONTRACTS AUG 29 2018**	
HDTRA11410075	$ 2,003,038	03/31/18	F.A.O. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS		Food and Agriculture Organization of the United Nations (FAO) for Support of Cooperation on Global Rinderpest Post-Eradication, Disease Surveillance and Associated Animal Health		
HDTRA114C0108	$ 2,623,395	01/09/19	SOFT TECH CONSULTING, INC.	Yes	Open Skies Management and Planning System (OSMAPS) Technical Support services contract	CUSTOM COMPUTER PROGRAMMING SERVICES	IT AND TELECOM- SYSTEMS ANALYSIS
HDTRA11610005	$ 2,559,097	11/18/18	PENNSYLVANIA STATE UNIVERSITY, THE		Emerging Infectious Diseases and Food Safety Implications of Bushmeat Consumption in Tanzania		
HDTRA11610014	$ 3,639,426	01/28/21	NATIONAL UNIVERSITY OF SINGAPORE		Investigating the Risk of Human Disease		

Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA116C0012	$ 184,493,891	05/26/21	BOOZ ALLEN HAMILTON INC.		Training Course: Network Operations Course; A&AS Services	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	SUPPORT- MANAGEMENT: OTHER
HDTRA116C0016	$ 4,026,105	03/14/18	DIAGNOSTIC MICROBIOLOGY DEVELOPMENT PROGRAM		Cambodia Diagnostic Microbiology Training Program	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	SUPPORT- PROFESSIONAL: OTHER
HDTRA116C0027	$ 4,823,032	05/10/21	NORTHROP GRUMMAN SYSTEMS CORPORATION		OSMAPS SW	CUSTOM COMPUTER PROGRAMMING SERVICES	IT AND TELECOM- SYSTEMS ANALYSIS
HDTRA116C0050	$ 13,081,262	06/20/19	BMJ PUBLISHING GROUP LTD			PERIODICAL PUBLISHERS	SUPPORT- PROFESSIONAL: OTHER
HDTRA11710008	$ 3,115,275	11/16/19	ORGANISATION MONDIALE DE LA SANTÉ "WORLD HEALTH ORGANISATION"		Strengthening Epidemiology and Public Health Laboratory Systems in Laos		
HDTRA11710009	$ 2,437,478	02/01/20	ORGANISATION MONDIALE DE LA SANTÉ "WORLD HEALTH ORGANISATION"		Strengthening Epidemiology and Public Health Laboratory Systems in Cambodia		
HDTRA11710037	$ 4,065,666	04/30/22	ECOHEALTH ALLIANCE INC.		Serological Biosurveillance for Spillover of Henipaviruses and Filoviruses		
HDTRA11710064	$ 4,391,444	10/01/22	ECOHEALTH ALLIANCE INC.		Understanding the Risk of Bat-borne Zoonotic Disease Emergency in Western Asia		
HDTRA117C0004	$ 3,446,964	06/14/19	CHULALONGKORN UNIVERSITY		Chulalongkorn Equipment Procurement & Installation	EDUCATIONAL SUPPORT SERVICES	LABORATORY EQUIPMENT AND SUPPLIES
HDTRA117C0019	$ 170,219,528	05/10/22	LEIDOS, INC.		Scientific & Technical Engagement Partnership Program (STEP)	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	SUPPORT- PROFESSIONAL: OTHER
HDTRA117C0067	$ 8,552,504	07/05/20	Technology Management Company, Inc.	Yes	Uzbekistan Biosciences Engagement Program	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES	SUPPORT- MANAGEMENT: OTHER
HDTRA117C0072	$ 2,640,994	07/16/22	WOOLPERT, INC.		Open Skies Target Contract	ENGINEERING SERVICES	SUPPORT- PROFESSIONAL: ENGINEERING/TECHNICAL
HDTRA11810021	$ 3,341,966	02/28/22	ORGANISATION INTERNAT POLICE CRIMINELLE		Interpol CRIMP GRANT		

Base Contract	Award Total Value With Options	Ultimate Completion Date	Vendor Name	Small Business	DTRA Description	NAICS Description	Product Service Code Description
HDTRA11310006					MICROBIOLOGY OF SELECT		
HDTRA1131003	$ 4,422,202	03/31/19	VANDERBILT UNIVERSITY MEDICAL CENTER		Human Monoclonal antibodies effort		
HDTRA113100	$ 3,555,616	08/14/18	UNIVERSITY OF MARYLAND		Aut Localization and delivery of therapeutics effort		
HDTRA11310038	$ 2,684,537	07/02/18	MASSACHUSETTS INSTITUTE OF TECHNOLOGY		NECLEOPORE MEMBRANE MIMICS AS SELECTIVE FILTERS		
HDTRA11310044	$ 2,775,000	08/25/18	UNIVERSITY OF WASHINGTON		Dual Functional Butyrylcholinesterase effort		
HDTRA113100	$ 4,446,488	02/02/20	UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL		PRINT Butyrylcholinesterase (BuChE) Delivery effort		
HDTRA1131004	$ 4,210,153	07/17/19	UNIVERSITY OF CALIFORNIA, LOS ANGELES		Multifunctional Gated Mesoporous Silica Nanoparticles effort		
HDTRA11310047	$ 4,377,507	06/27/19	UNIVERSITY OF WASHINGTON		Gram Negative bioactive antibiotic drug delivery effort		
HDTRA11310049	$ 3,923,742	09/19/18	SYNERGENE THERAPEUTICS INC		Nanomedicine Crossing the BBB effort		
HDTRA113C0064	$ 6,968,715	09/29/18	PENNSYLVANIA STATE UNIVERSITY, THE		Predictive In Vitro Models to Assess Biodefense Vaccines	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	R&D- DEFENSE OTHER: SERVICES (BASIC RESEARCH)
HDTRA113C0088	$ 4,522,210	08/15/18	L-3 Applied Technologies, Inc.		MEEC and SGEMP physics and enhancements	RESEARCH AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	R&D- DEFENSE OTHER: OTHER (APPLIED RESEARCH/EXPLORATORY DEVELOPMENT)
HDTRA114100	$ 2,500,000	02/28/19	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO		HUMAN STRATUM CORNEUM PROTEIN AND LIPID DOMAIN		

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4. University of Kinshasa
5. University of Lubumbashi

ETHIOPIA
6. Jimma University
7. University of Addis Ababa
8. Mekelle University

KENYA
9. University of Nairobi
10. Moi University

RWANDA
11. University of Rwanda
12. University of Global Health Equity

SENEGAL
13. Université Cheikh Anta Diop

TANZANIA
14. Muhimbili University of Health & Allied Sciences
15. Sokoine University of Agriculture

UGANDA
16. Mbarara University of Science & Technology
17. Makerere University

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18. Félix Houphouët-Boigny

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19. University of Liberia

Introducing and Welcoming you to Africa One Health University Network (AFROHUN)

Current AFROHUN Network Reach

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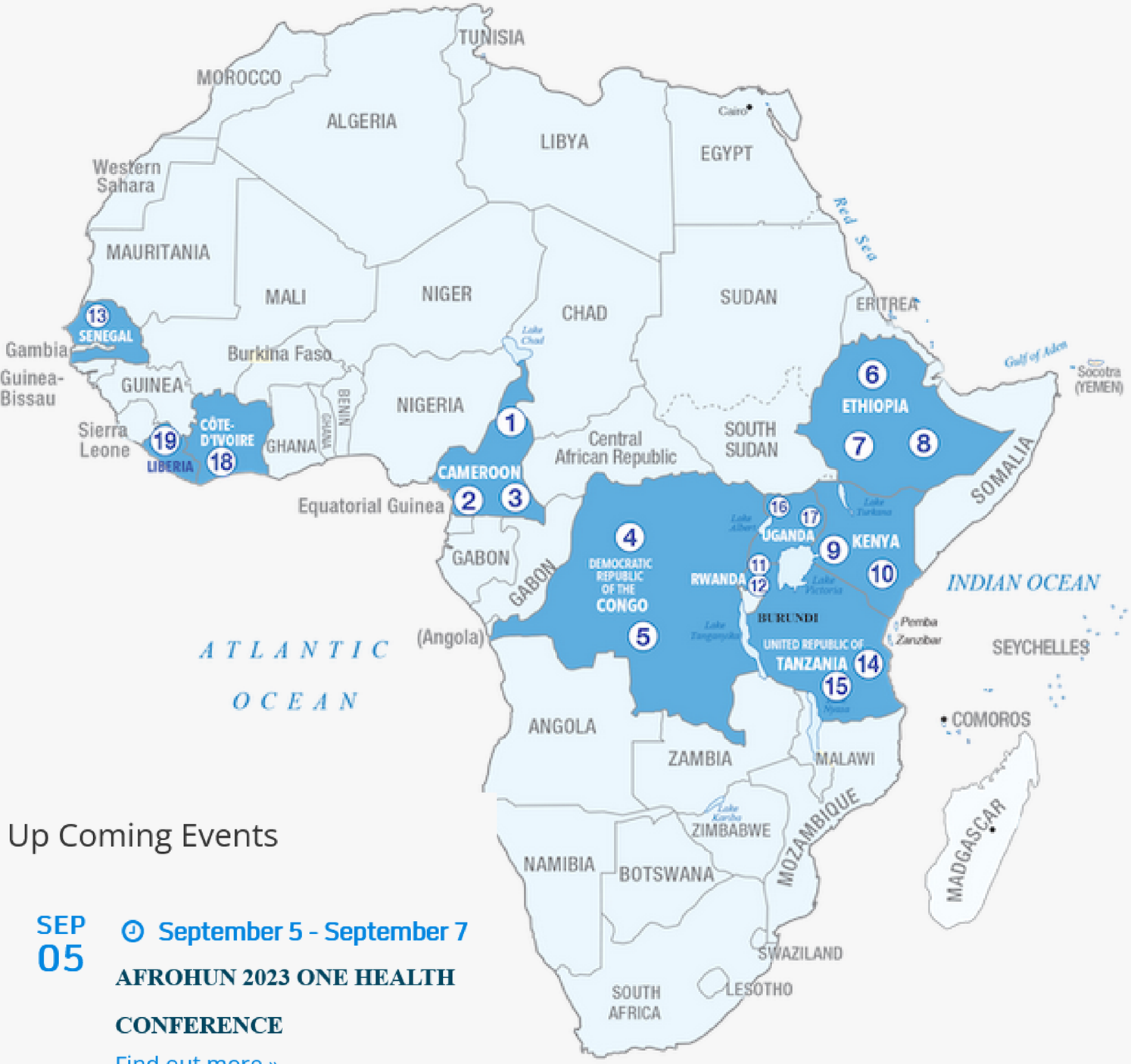
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September 5 - September 7

AFROHUN 2023 ONE HEALTH CONFERENCE

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10	27	19	9837	300	2863
Countries	Institutions	Participating Universities	Total Students Trained	Faculty Trained	in-service professionals



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Metabiota - Viral Surveillance for the PREDICT Program 20150410

10/1/14 - 6/1/17

Investigator: Charles Chiu, MD, PhD

Sponsor: Metabiota, Inc

Visit project website

Location(s): Rwanda; Uganda; Tanzania; Cameroon; Congo (Kinshasa); Congo (Brazzaville); Gabon; China; Bangladesh; Nepal; Cambodia; Indonesia; Viet Nam; Laos; Malaysia; Thailand; Mexico; Bolivia; Brazil; Peru

Description

PREDICT's surveillance for emerging pathogens focuses on areas of the world at the highest risk for zoonotic disease emergence. The goal is to move countries away from a reactive post-outbreak response to a proactive approach in which pathogens of pandemic potential are discovered at their source before diseases have the opportunity to spillover.

Our staff and partners focus surveillance on species most likely to serve as reservoirs of disease, and we work at human-animal interfaces where pathogen transmission is most likely to occur.

Traditional public health and disease surveillance systems have ignored the inextricable link between animals, humans and the environment. PREDICT has been instrumental in broadening understanding, improving capabilities, and linking key stakeholders to build a more comprehensive and flexible approach to surveillance. Rather than prescribing an across-the-board surveillance plan, we allow project leads in each country to establish targeted, measurable, adaptive, and responsive approaches that are integrated across health sectors.

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Metabiota - Viral Surveillance for the PREDICT Program 20150410

10/1/14 - 6/1/17

Investigator: Charles Chiu, MD, PhD

Sponsor: Metabiota, Inc

Visit project website

Location(s): Rwanda; Uganda; Tanzania; Cameroon; Congo (Kinshasa); Congo (Brazzaville); Gabon; China; Bangladesh; Nepal; Cambodia; Indonesia; Viet Nam; Laos; Malaysia; Thailand; Mexico; Bolivia; Brazil; Peru

Description

PREDICT's surveillance for emerging pathogens focuses on areas of the world at the highest risk for zoonotic disease emergence. The goal is to move countries away from a reactive post-outbreak response to a proactive approach in which pathogens of pandemic potential are discovered at their source before diseases have the opportunity to spillover.

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WHAT WE DO



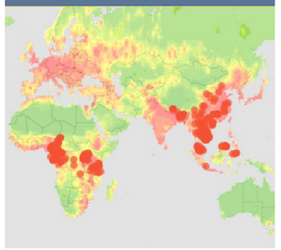
The core components that make up the PREDICT project

WHERE WE WORK



Where PREDICT teams are working throughout the world

WHAT WE'VE FOUND



A glance at the PREDICT's findings

PUBLICATIONS



Works produced by and through the work of PREDICT

NEWS & IMPACT



Impactful stories from PREDICT activities around the world

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ABOUT PREDICT

PREDICT is enabling global surveillance for pathogens that can spillover from animal hosts to people by building capacities to detect and discover viruses of pandemic potential. The project is part of USAID's Emerging Pandemic Threats program and is led by the UC Davis One Health Institute. The core partners are USAID, EcoHealth Alliance, Metabiota, Wildlife Conservation Society, and Smithsonian Institution. Contact us at predict@ucdavis.edu.

- PREDICT Flyer (PDF)
- Our first 5 years

LATEST NEWS

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- CAN SAVING ANIMALS PREVENT THE NEXT PANDEMIC?
- MERS-LIKE CORONAVIRUS IDENTIFIED IN UGANDAN BAT
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One Health Institute Leadership Team

Jonna Mazet



Executive Director, UC Davis One Health Institute

Jonna Mazet, DVM, MPVM, PhD, is a Professor of Epidemiology and Disease Ecology and Executive Director of the One Health Institute in the UC Davis School of Veterinary Medicine, where she focuses on global health problem solving, especially for emerging infectious disease and conservation challenges. Dr. Mazet is active in international One Health research programs, most notably in relation to disease transmission among wildlife, domestic animals, and people and the ecological drivers of disease emergence. Currently, she is the Global Director of a $175 million viral emergence early warning project, named PREDICT, that has been developed with the US Agency for International Development's (USAID) Emerging Pandemic Threats Program. She was elected to the US National Academy of Medicine in 2013 in recognition of her successful and innovative approach to emerging environmental and global health threats and serves on the National Academies' Forum on Microbial Threats, as well as chairs the Academies' One Health Work Group.

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One Health Institute Leadership Team

Jonna Mazet



Executive Director, UC Davis One Health Institute

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PREDICT Home
What We Do
Where We Work
What We've Found
Publications
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One Health In Action

PREDICT

THE WORLD'S MOST COMPREHENSIVE ZOONOTIC DISEASE SURVEILLANCE & CAPACITY DEVELOPMENT PROGRAM

TRAINED 3,300 government personnel, physicians, veterinarians, resource managers, laboratory technicians, and students in One Health skills including biosafety, surveillance, lab techniques, and disease outbreak investigation.



SAMPLED 74,000+ at-risk people, live- stock, and wildlife (nonhuman primates, bats, rodents, and other wild animals (including bushmeat samples) at human-animal interfaces with high-risk and opportunity for viral spillover.



DEVELOPING & OPTIMIZING low-cost methods for the detection of viral threats like Ebola and influenza and for the discovery of new viruses with 60 labs including those in national lab systems in up to 30 countries around the world.



DETECTING more than 1,000 unique viruses in animals and humans: 820 novel viruses and 182 known viruses (including Ebola and SARS) – the most comprehensive viral detection and discovery effort to date.



Edward Rubin

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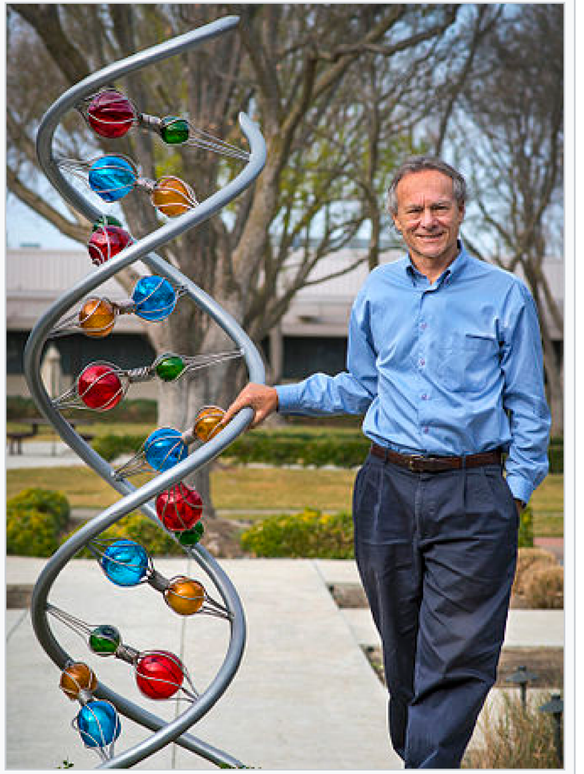
From Wikipedia, the free encyclopedia

For the Los Angeles-based entertainment lawyer, see Edward Rubin (attorney).

Edward Rubin is the chief scientific officer at Metabiota, a company that works on epidemic risk and infectious diseases. From 2002 to 2016, he was a researcher at the Lawrence Berkeley National Laboratory and the director of the Department of Energy's Joint Genome Institute.[1] In 2012, he was named the Charles J. and Lois B. Epstein Visiting Professor at the University of California San Francisco.[2]

Rubin performed testing on the Neanderthal genome, which suggests human and Neanderthal DNA are some 99.5 percent to nearly 99.9 percent identical.[3]

He is on the board of directors of the Global Virome Project.[4]



References [edit]

1. ^ "JGI Director to Step Down to Assume Scientific Helm of Startup - DOE Joint Genome Institute". *DOE Joint Genome Institute*. 10 March 2016. Retrieved 16 February 2018.
2. ^ Norris, Jeffrey. "Personalized Medicine From Genomics and Bioinformatics Highlighted at UCSF Genetics Symposium". *UC San Francisco*. Retrieved 16 February 2018.
3. ^ Than, Ker (15 November 2006). "Neanderthal: 99.5 Percent Human". *Live Science*. Retrieved 16 February 2018.
4. ^ "Leadership Team".



Andrew Clements

U.S. Agency for International Development, Washington, DC, USA

Andrew Clements, PhD, is a Senior Scientific Advisor for the Emerging Threats Division in the U.S. Agency for International Development's Bureau for Global Health. He received his Ph.D. in Anaerobic Microbiology from Virginia Tech and completed his post-doctoral training in biochemistry at the National Institutes of Health. Between 1997 and 2005, he served as an infectious disease advisor at USAID focusing on the development, management, and monitoring of international programs to address malaria, tuberculosis, antimicrobial resistance, and infectious disease surveillance. Since 2005, he has managed a number of projects (PREDICT, PREVENT) and partnerships with the Food and Agriculture Organization of the UN and the World Health Organization that support prevention, detection, and response to emerging zoonotic threats in developing countries. He also analyzes trends for emerging zoonotic threats and has participated in USAID's responses to new diseases, including H5N1 and H7N9 avian influenza, H1N1 pandemic influenza, MERS-CoV, and Ebola.

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USAID Andrew Clements



Andrew Clements

U.S. Agency for International Development, Washington, DC, USA

Andrew Clements, PhD, is a Senior Scientific Advisor for the Emerging Threats Division in the U.S. Agency for International Development's Bureau for Global Health. He received his Ph.D. in Anaerobic Microbiology from Virginia Tech and completed his post-doctoral training in biochemistry at the National Institutes of Health. Between 1997 and 2005, he served as an infectious disease advisor at USAID focusing on the development, management, and monitoring of international programs to address malaria, tuberculosis, antimicrobial resistance, and infectious disease surveillance. Since 2005, he has managed a number of projects (PREDICT, PREVENT) and partnerships with the Food and Agriculture Organization of the UN and the World Health Organization that support prevention, detection, and response to emerging zoonotic threats in developing countries. He also analyzes trends for emerging zoonotic threats and has participated in USAID's responses to new diseases, including H5N1 and H7N9 avian influenza, H1N1 pandemic influenza, MERS-CoV, and Ebola.

The Global Virome Project [edit]

The **Global Virome Project (GVP)** is an American-led international collaborative research initiative based at the One Health Institute at the University of California, Davis.[14][15] The project was co-launched by EcoHealth Alliance president Peter Daszak, Nathan Wolfe and Edward Rubin of Metabiota, and former Chinese Center for Disease Control and Prevention director George F. Gao.[16]

The goal of the Global Virome Project (GVP) is to identify and prevent future virus outbreaks.[17] The GVP is centered on the massive collection and sequencing of the planet's unknown viruses, with an estimated 1.6 million viral species yet to be discovered in mammal and bird populations. Of these, 631,000 to 827,000 have zoonotic potential.[17] The cost of identifying these unidentified viruses is a major limitation of the GVP, with a total cost estimate of $1.2 billion. That being said, preventing an outbreak is still less costly than reacting to one, with the total estimated cost of the ongoing COVID-19 pandemic estimated at more than $16 trillion.[18] The Global Virome project also aims to boost infectious disease surveillance around the globe by using low cost sequencing methods in high risk countries to prevent disease outbreaks by expanding on the efforts of the USAID (agency for international development) EPT (Emerging Pandemic Threats) PREDICT project. The PREDICT project was founded to discover unidentified viral species by sampling animals and humans in countries with high zoonotic disease threat and determine the mechanisms that cause viral spillover into human populations. The Predict project found over 1000 unique viruses in animals and humans.[19]

The Global Virome Project could aid in pandemic surveillance, diagnosis techniques and prevention strategies, and determine the need for pre-emptive production of vaccine and other countermeasures for candidate high-risk viruses. The GVP can also provide further insights into viral pathogenicity and possible biosecurity methods in agriculture.[16]

The Global Virome Project was supposed to be begin sampling wild animal populations in 2020 but were delayed due to the COVID-19 pandemic.[20]

EMERGING PATHOGEN SURVEILLANCE WITH JONNA MAZET

ABOUT PREDICT

PREDICT is enabling global surveillance for pathogens that can spillover from animal hosts to people by building capacities to detect and discover viruses of pandemic potential. The project is part of USAID's Emerging Pandemic Threats program and is led by the UC Davis One Health Institute. The core partners are USAID, EcoHealth Alliance, Metabiota, Wildlife Conservation Society, and Smithsonian Institution. Contact us at predict@ucdavis.edu.



- PREDICT Flyer (PDF)
- Our first 5 years

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OHW Next Generation - Pre-Application Conference Participants
RFA No.: 7200AA19RFA00004
Washington, DC
Monday, November 19, 2018

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David	O'Connor	Institutional Partnership	Union of Medical Care and Relief	david.o'connor@uocsm.us

Subaward ID	Awardee	Prime Awardee	Obligated	Modified
US1AM_USLMUS0004-AID624A1400003-a175a45b	Metabiota P	Cooperative For Assistance And Relief Everywhere	$124.0K	11/25/20
Sub Description CONTINUUM OF PREVENTION CARE AND TREATMENT OF HIV/AIDS OF MOST-AT-RISK POPULATIONS IN CAMEROON				
Prime Description CONTINUUM OF PREVENTION CARE AND TREATMENT OF HIV/AIDS IN MOST AT RISK POPULATIONS IN CAMEROON				
SH1706-AIDOAAA1400060-716ccac7	Metabiota Cameroon P	Population Council	$74.6K	04/07/20
Sub Description METABIOTA WILL IMPLEMENT A PILOT STUDY TO EVALUATE AN UPDATED PEOPLE LIVING WITH HIV STIGMA INDEX IN CAMEROON				
Prime Description APP FOR AAD 936-3090				
SH1706-AIDOAAA1400060-5111ad11	Metabiota Cameroon P	Population Council	$73.9K	01/29/20
Sub Description Metabiota will implement a pilot study to evaluate an updated people living with HIV stigma index in Cameroon				
Prime Description APP FOR AAD 936-3090				
A15-0146-S005-AIDOAAA1400102-7fecb547	Metabiota P	Davis University Of California	$1.2M	07/31/19
Sub Description Emerging Pandemic Threats Program 2 PREDICT-2				
Prime Description EMERGING PANDEMIC THREATS-2				
A15-0146-S005-AIDOAAA1400102-c1e5f48e	Metabiota P	Davis University Of California	$1.6M	06/26/19
Sub Description Emerging Pandemic Threats Program 2 PREDICT-2				
Prime Description EMERGING PANDEMIC THREATS-2				
US1AM-USLMUS0004-AID624A1400003-0d87d6c7	Metabiota P	Cooperative For Assistance And Relief Everywhere	$362.1K	05/31/18
Sub Description CONTINUUM OF PREVENTION, CARE AND TREATMENT(COPCT) OF HIV/AIDS WITH MOST AT-RISK-POPULATIONS(CHAMP) IN CAMEROON				
Prime Description CONTINUUM OF PREVENTION CARE AND TREATMENT OF HIV/AIDS IN MOST AT RISK POPULATIONS IN CAMEROON				

Black & Veatch-Ukraine-Cameroon, BSL-3 laboratory

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Project Name	Location	Client
CBEP Ukraine Phase II — BTRIC TO 1	Ukraine	Defense Threat Reduction Agency (DTRA)

Black & Veatch designed and constructed a new emergency operation building with administrative offices for the Cameroon Ministry of Health. We executed this large-scale CBEP effort that included engineering design, renovation/construction, CBEP and operations and maintenance (O&M) training, equipping, commissioning, third party validation, international certification, and sustainment support and transition at 15 14 laboratory facilities (14 13 BSL-2 and 1 BSL-3 CRL), an additional 18 BS&S site upgrades, an extensive program of collaborative biological research, and support to achieve initial operational capability/full operational capability. It included all Scope of Work (SOW) elements of TO RFP 0022 but on a national Threat Agent Detection and Response system scale across Ukraine.

"Black & Veatch utilized local subcontractors to help design and construct the first BSL-3 laboratory in the region and provided enhanced equipment and training to effectively, safely and securely identify especially dangerous pathogens."

"Black & Veatch provided recipient laboratory staff all requisite training, and ensured the B&V constructed facilities met biological safety, security and sustainability requirements."

Metabiota contracts: Tanzania, Sierra Leone, Cameroon, Congo, Chad, Burundi

HDTRA11410052	Metabiota P	Defense Threat Reduction Agency [DoD]	Project	$731.8K	08/05/14	09/06/19	01/22/21
Description EVALUATING ZOONOTIC VIRAL SHARING AMONG BATS, PRIMATES AND PEOPLE IN A HIGH RISK TRANSMISSION INTERFACE IN SOUTHERN TANZANIA							
N002441710015	Metabiota P	NAVSUP Fleet Logistics Center San Diego [DoD - USN - NAVSUP]	Project	$1.8M	02/24/17	02/23/20	09/27/19
Description HIV/AIDS CARE & TREATMENT CAPACITY REINFORCEMENT AMONG THE REPUBLIC OF SIERRA LEONE ARMED FORCES							
N002441510067	Metabiota P	NAVSUP Fleet Logistics Center San Diego [DoD - USN - NAVSUP]	Project	$2.4M	09/01/15	08/30/19	10/15/18
Description BASIC AWARD FOR METABIOTA-CONGO							
N002441510066	Metabiota P	NAVSUP Fleet Logistics Center San Diego [DoD - USN - NAVSUP]	Project	$850.0K	09/01/15	08/30/19	10/15/18
Description BASIC AWARD FOR METABIOTA-CHAD							
N002441410067	Metabiota P	NAVSUP Fleet Logistics Center San Diego [DoD - USN - NAVSUP]	Project	$2.4M	09/30/14	01/31/19	09/16/18
Description OPTIMIZING PMTCT SERVICES AND STREGTHENING LABORATORY SYSTEMS IN MILITARY HEALTH FACILITIES IN FOUR (4) PEPFAR PRIORITY REGIONS OF CAMEROON.							
HDTRA11410053	Metabiota P	Defense Threat Reduction Agency [DoD]	Project	$1.9M	08/07/14	08/06/17	11/16/17
Description ZOONOTIC SELECT AGENTS IN TANZANIA A ONE HEALTH APPROACH TO RIFT VALLEY FEVER AND BRUCELLOSIS SURVEILLANCE							
N002441510068	Metabiota P	Department of Defense	Project	$300.0K	09/01/15	08/31/17	06/06/16
Description BASIC AWARD FOR METABIOTA-BURUNDI							
U2GGH001800	Metabiota P	Centers for Disease Control and Prevention [HHS]	Cooperative	$1.2M	06/01/16	05/31/20	06/03/16
Description GLOBAL HEALTH SECURITY PARTNER ENGAGEMENT: EXPANDING EFFORTS AND STRATEGIES TO PROTECT AND IMPROVE PUBLIC HEALTH GLOBALLY							
N002441510009	Metabiota P	Department of Defense	Project	$420.0K	01/20/15	07/19/16	02/05/15
Description ESTABLISHING SEXUAL NETWORKS FOR HIV TRANSMISSION AMONG ACTIVE DUTY AND OTHER KEY POPULATIONS.							

HDTRA11410053	Metabiota P	Defense Threat Reduction Agency [DoD]	Project	$1.9M	08/07/14	08/06/17	11/16/17
Description ZOONOTIC SELECT AGENTS IN TANZANIA A ONE HEALTH APPROACH TO RIFT VALLEY FEVER AND BRUCELLOSIS SURVEILLANCE							
N002441510068	Metabiota P	Department of Defense	Project	$300.0K	09/01/15	08/31/17	06/06/16
Description BASIC AWARD FOR METABIOTA-BURUNDI							
U2GGH001800	Metabiota P	Centers for Disease Control and Prevention [HHS]	Cooperative	$1.2M	06/01/16	05/31/20	06/03/16
Description GLOBAL HEALTH SECURITY PARTNER ENGAGEMENT: EXPANDING EFFORTS AND STRATEGIES TO PROTECT AND IMPROVE PUBLIC HEALTH GLOBALLY							
N002441510009	Metabiota P	Department of Defense	Project	$420.0K	01/20/15	07/19/16	02/05/15
Description ESTABLISHING SEXUAL NETWORKS FOR HIV TRANSMISSION AMONG ACTIVE DUTY AND OTHER KEY POPULATIONS.							
N002441410013	Metabiota P	Department of Defense	Project	$1.5M	12/13/13	12/12/14	07/08/14
Description HIV PREVENTION, CARE AND TREATMENT SERVICES FOR CENTRAL AFRICAN MILITARY							
N002441320001	Metabiota P	Department of Defense	Cooperative	$649.9K	01/30/13	01/29/15	05/04/14
Description HIV PREVENTION, SURVEILLANCE, AND BEHAVIORAL RESEARCH IN THE DEMOCRATIC REPUBLIC OF CONGO MILITARY							
N002440910008	Metabiota P	Department of the Navy [DoD]	Project	$2.5M	08/17/09	09/17/13	10/05/12
Description IMPROVING HIV/AIDS PREVENTION AND SURVEILLANCE IN CENTRAL AFRICAN MILITARIES							
W81XWH1120200	Metabiota P	Department of the Army [DoD]	Cooperative	$126.9K	09/19/11	01/18/12	10/21/11
Description IDENTIFICATION OF BIOMARKERS IN HUMAN & NONHUMAN PRIMATE PRE-SYMPTOMATIC CLINICAL SAMPLES-LASSA FEVER IN SIERRA LEONE							

Prime Grants 23 | Sub Grants 14

Award ID	Awardee	Awarding Agency	Type	Obligated	Start	End	Modified
DP1OD000370	Metabiota P	National Institutes of Health [HHS]	Project	$1.3M	09/30/05	07/31/12	08/22/11
Description NIH DIRECTOR'S PIONEER AWARD							
SLMAQM10GR073	Metabiota P	Department of State	Project	$585.4K	09/22/10	11/30/12	08/20/11
Description BUILDING SCIENTIFIC AND LABORATORY CAPACITY FOR DETECTION OF EMERGING PANDEMIC THREATS IN PAKISTAN, MALAYASIA, AND AFRICA							
RC2CA148534	Metabiota P	National Institutes of Health [HHS]	Project	$1.8M	09/30/09	08/31/11	10/05/10
Description IDENTIFYING NOVEL VIRUSES IN HUMAN MALIGNANCY							

AWARDEE

Metabiota [P]

UEI: W7E4TAVCRLD6 • CAGE: 56SP4

Awardee Type	Parent
Website	http://metabiota.com
Headquarters	San Francisco, CA United States
Most Recent Award	Oct. 1, 2021
Contracts	
Set-Aside %	~0%
Largest Major Agency (Awarding)	Defense Threat Reduction Agency (100%)
Largest Sub-Agency (Awarding)	Defense Threat Reduction Agency (100%)
Largest NAICS	541712 - Research And Development In The Physical, Engineering, And Life Sciences (Except Biotechnology) (100%)
Largest PSC	AM11 - International Affairs R&D Services; International Affairs; Basic Research (100%)
Grants	
Largest Major Agency (Awarding)	Department of the Navy (33%)
Largest Sub-Agency (Awarding)	NAVSUP Fleet Logistics Center San Diego (33%)
Largest Grant Program	12.350 - Department of Defense HIV/AIDS Prevention Program (55%)

Metabiota Partners

TEAMING PARTNERS

Download

Disclosed Awardee Sub and Prime Contract and Grant Relationships

* Metabiota

10 Shown

Prime	Sub	Type	Awards	Total Awarded	Most Recent	Explore
Black & Veatch Special Projects [C]	Metabiota [P]*	Contract	7	$27.0M	06/10/20	Explore
ICF [C]	Metabiota [P]*	Contract	4	$835.3K	02/13/20	Explore
Cooperative For Assistance And Relief Everywhere [P]	Metabiota [P]*	Grant	2	$486.1K	09/18/19	Explore
Davis University Of California [C]	Metabiota [P]*	Grant	9	$30.9M	07/11/19	Explore
Metabiota [P]*	Care And Health Program [P]	Grant	1	$46.0K	10/05/16	Explore
San Francisco Regents Of The University Of California [C]	Metabiota [P]*	Contract	1	$66.3K	09/16/11	Explore

CONTRACT AWARDS

Prime Contracts Awarded to Metabiota

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5 Shown

Keywords

Award ID	Awardee	Awarding Agency	Potential Value	Start	Potential End	Modified
W911QY18D0174-0001	Metabiota P	ACC Aberdeen Proving Ground	$1.0K	11/17/17	12/05/17	03/01/22
Description START OF CONTRACT MEETING						
HSHQDC13CB0048	Metabiota P	DHS Office of the Chief Procurement Officer	$349.5K	09/27/13	03/30/15	09/14/20
Description IGF::CT::IGF THE DEPARTMENT OF HOMELAND SECURITY COST PLUS FIXED FEE CONTRACT HSHQDC-13-C-B0048 IS PROVIDING FUNDS IN THE AMOUNT OF $349,512.84 TO METABIOTA INC FOR VALIDATION OF ANIMAL MODELS FOR VIRAL HEMORRHAGIC FEVER SYNDROME USING ACUTE HUMAN DATA. ALL WORK SHALL BE DONE IN ACCORDANCE WITH THE STATEMENT OF WORK (SOW). ATTACHMENT 1: STATEMENT OF WORK						
HDTRA114C0104	Metabiota P	Defense Threat Reduction Agency	$23.9M	02/10/14	11/15/16	03/04/20
Description PROJECT COORDINATION (TASK 1)						
HSHQDC10P00100	Metabiota P	DHS Office of the Chief Procurement Officer	$90.0K	05/31/17	09/28/11	07/28/17
Description DIVISION: CHEMICAL & BIOLOGICAL PPA: CHEMICAL & BIOLOGICAL THRUST: BIOLOGICAL PROGRAM: SURVEILLANCE AND DETECTION - R&D PROJECT: BIOASSAYS - NEXT GENERATION PERFORMER: GLOBAL VIRAL FORECASTING, INC. APPROPRIATION YEAR: FY10 (02 FUNDS) BUDGET AUTHORITY: THREE-YEAR R&D FUNDS PROJECT MANAGER: NELS OLSON LEAD SUPPORT STAFF: AMANDA CLAGGETT ALC: 70-08-1513 APPS: 70020800 DESCRIPTION: THE PURPOSE OF THIS REQUISITION IS TO PROVIDE FUNDING FOR AN ANNUAL MEMBERSHIP/DRY SPONSORSHIP OF THE GLOBAL VIRAL FORECASTING (GVF)						
HDTRA112C0024	Metabiota P	Defense Threat Reduction Agency	$3.2M	09/27/16	02/14/15	09/27/16
Description RESEARCH PROJECTS IN CENTRAL AND WEST AFRICA.						

Description

Provide the JPEO-CBD with mission-essential contracted support for the Research, Development, Acquisition and Production/Procurement (RDAP) of Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives CBRNE Defense Systems, Capabilities, Equipment, Supplies and Material; Installation Protection; Radiological/Nuclear Defense Systems, and CBRNE Information Systems. The JPEO-CBD intends to utilize the JE-RDAP contract to execute RDAP activities, in order to provide the capability of CBRNE Defense Systems, Capabilities, Equipment, Supplies and Material; Radiological/Nuclear Defense Systems, and CBRNE Information Systems to the Warfighter. The RDAP activities to be performed under this contract are for research and development of CBRNE Defense systems, capabilities, equipment, supplies and material subject to the acquisition policies and guidance of the Operation of the Defense Acquisition System (DODI 5000.02) and production/procurement of these future developed CBRNE defense capabilities.

Black & Veatch + Metabiota Contracts

Awardee Include Metabiota

Prime Awardee Include Black & Veatch Special Projects

IDV Awards 0 | Prime Awards 0 | Sub Awards 7

Subaward ID	Awardee	Prime Awardee	Prime Awarding Agency	Obligated	Modified
13-0045D	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$69.5K	09/29/20
Sub Description SME 1 AND SME 2 MENTORSHIP					
Prime Description PMO (LEVEL OF EFFORT)					
13-0045C	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$14.5M	09/29/20
Sub Description Consultant Labor					
Prime Description PMO (LEVEL OF EFFORT)					
18-5006	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$990.0K	10/29/19
Sub Description TECHNICAL EXPERTISE FOR DESIGN REVIEWS, LABORATORY AND FIELD EPIDEMIOLOGY TRAINING PROGRAM TRAINING AND OTHER SUPPORT.					
Prime Description CONDUCT LABORATORY RENOVATIONS, PROCURE AND INSTALL EQUIPMENT, AND CONDUCT TRAINING IN IRAQ.					
18-1000	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$60.3K	06/28/19
Sub Description Implementation of biosafety and biosecurity - Senegal FFP TO - Mod 002 lab upgrades					
Prime Description COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM (CBEP) LABORATORY STRENGTHENING, SENEGAL					
16-0291	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$4.0M	12/27/18
Sub Description Labor Support - Researchers					
Prime Description PMO, SUSTAINMENT&TRAINING					
17-0002	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$1.0M	03/26/18
Sub Description ESTABLISHING SCIENTIFIC, FIELD AND LABORATORY RESEARCH FOR QUALITATIVE AND QUANTITATIVE DATA ANALYTICS.					
Prime Description LABORATORY EQUIPMENT PLANNING					
13-0045	Metabiota	Black & Veatch Special Projects	Defense Threat Reduction Agency	$6.3M	11/26/13
Sub Description Provide Integration, Planning, Organization, Management,					
Prime Description PMO (LEVEL OF EFFORT)					

SUBCONTRACT

13-0045C

Overview | Hierarchy | Related 67 | History 1 | Prime Funding | Prime Overview

OVERVIEW

Sub Awardee	Metabiota P
Sub Description	Consultant Labor
Total Awarded	$14,525,531.01
Most Recent Award Date	Sept. 21, 2012
Place of Performance	San Francisco, California 94104-2114 United States
Prime Awardee	Black & Veatch Special Projects C
Prime Project Title	None
Prime Award	HDTRA108D0007-0004

AWARD HIERARCHY

Indefinite Delivery Contract	Delivery Order	Subcontract
HDTRA108D0007	HDTRA108D0007-0004	13-0045C

SUBCONTRACT

13-0045

OVERVIEW

Sub Awardee	Metabiota P
Sub Description	Provide Integration, Planning, Organization, Management,
Total Awarded	$6,287,104.00
Most Recent Award Date	Jan. 17, 2013
Place of Performance	Kiev Ukraine
Prime Awardee	Black & Veatch Special Projects C
Prime Project Title	DTRA - Ukraine
Prime Award	HDTRA108D0007-0004

AWARD HIERARCHY

Indefinite Delivery Contract	Delivery Order	Subcontract
HDTRA108D0007	HDTRA108D0007-0004	13-0045

PRIME STATUS

Period of Performance

9/20/12	10/13/20	10/13/20
Start Date	Current End Date	Potential End Dat

Overview | Hierarchy | Related 67 | History 1 | Prime Funding | Prime Overview

Obligations

$77.7M	$116.6M	$116.6M
Total Obligated	Current Value	Potential Value

67% Funded

PRIME OVERVIEW

Original Description	PMO (LEVEL OF EFFORT)
Awarding / Funding Agency	Defense Threat Reduction Agency (DTRA) [DoD]
NAICS	Not Reported
PSC Category	R799 - Support- Management: Other
Pricing	Cost Plus Fixed Fee
Place of Performance	Ukraine
Set Aside	None
Extent Competed	Full And Open Competition After Exclusion Of Sources

RELATED SUBCONTRACTS

Other Subcontracts Under the Same Prime Contract

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5 Shown

Keywords

Subaward ID	Awardee	Prime Awardee	Prime Awarding Agency	Obligated	Modified
19-6161	Eric Richard Tremont P	Black & Veatch Special Projects	Defense Threat Reduction Agency	$771.4K	12/28/20
Sub Description WRITING SERVICES					
19-6163	Oxford Nanopore Technologies C	Black & Veatch Special Projects	Defense Threat Reduction Agency	$58.7K	12/28/20
Sub Description LAB SUPPLIES					
17-6076	Smart Difens, Tov P	Black & Veatch Special Projects	Defense Threat Reduction Agency	$12.0M	11/25/20
Sub Description DESIGN WORKS					
18-6109	Diversified Laboratory Sciences P	Black & Veatch Special Projects	Defense Threat Reduction Agency	$4.2M	11/25/20
Sub Description Training Workshops					
17-6099	Kyiv Lengvich Servises, Tov P	Black & Veatch Special Projects	Defense Threat Reduction Agency	$174.1K	11/25/20
Sub Description TRANSLATION SERVICES					

* "Epidemiological Monitoring Station (EMS)" is the term used by the government of Azerbaijan. This term is equivalent to the term "Diagnostic Laboratory (DL)" in CBEP narratives of projects in other partner nations.

Ministry of Health (MOH), State Veterinary Service, and MOD on the commissioning process and the GoAJ on budget estimates, equipment and facility maintenance, procurement, and resupply distribution. DoD is working with the GoAJ on formal adoption of facility staffing plans, including negotiations of retention agreements with key staff members. DTRA agreed to conduct a site assessment in coordination with Ministers in Nakhchivan to take place in late October 2012. MOH and the State Veterinary Service both repeatedly confirmed the intent of the GoAJ to expand the Electronic Integrated Disease Surveillance System (EIDSS) into Nakhchivan, so this opportunity will also be explored during the visit.

At its ER, the Government of Kazakhstan (GoK) reaffirmed its commitment to the Central Reference Laboratory (CRL) project and offered to develop a list of biological agents to be studied at the future facility. The GoK agreed to explore acquiring funds out of an emergency reserve to complete the upgrade to the CRL's utilities infrastructure. In addition, the GoK agreed to coordinate closely with DoD regarding its renovation of the utilities infrastructure. The GoK agreed to help to facilitate the registration of scientific materials and equipment purchased by DoD for use in Kazakh labs. Finally, the ER resulted in agreement to correct a deficiency in the existing legal agreements to ensure the smooth transfer of the CRL and the biological safety-level three (BSL-3) laboratory in Otar to the GoK upon completion.

At the Ukraine ER, DoD confirmed the veterinary executive agents' interest in implementing CBEP, including implementation of the animal health DSDDR network. In addition, DoD confirmed the commitment of the Government of Ukraine to consolidate the animal biological agents and toxins and other pathogens that may cause public health emergencies of international concern collections at the future Central Diagnostic Facility in Kharkiv. The Government of Ukraine plans to continue using its reporting system instead of EIDSS; DoD requested information and access to this system so that U.S. experts can determine ways to integrate this system into animal health DSDDR capabilities and offer recommendations for improvement, if any. Transfer of three select agents from the Lviv Research Institute for Epidemiology and Hygiene (LRIEH) to the BSL-3 CRL in Odessa for consolidation purposes (see Section 4.6) remains an area of tension between CBEP and MOH. The U.S. Ambassador to Ukraine, senior DoD officials, and Senator Richard Lugar discussed this issue with senior Ukrainian officials, including the Minister of Health, and expect a response from the Government of Ukraine in early 2013.

4.6. Ukraine

FY 2014 – FY 2018 Five-Year Plan, Purpose, and Resources: DoD expects to complete CBEP engagement in Ukraine by the end of FY 2017, completing BS&S upgrades to the DSDDR network for both MOH and Ministry of Agrarian Policy, which is represented by the State Committee of Veterinary Medicine of Ukraine and Ukrainian Academy of Agrarian Science. MOH's DSDDR network will consist of nine BSL-2 DLs, one training center at the Central Sanitary and Epidemiological Station in Kyiv, and one BSL-3 CRL at the Ukrainian Research and Anti-Plague Institute (URAPI) in Odessa. The veterinary DSDDR network will consist of a BSL-3 Central Diagnostic Facility in Kharkiv, complete BS&S and DSDDR upgrades at 11 BSL-2 Regional Diagnostic Veterinary Laboratories, and a Veterinary Training Center at the Institute of Veterinary Medicine in Kyiv. The animal health project also will include biosecurity upgrades at the interim biological agent repository at the State Scientific-Control Institute of Biotechnology and Microorganism Strains in Kyiv. Sustainment support and training will be provided at all aforementioned DSDDR sites. By the end of FY 2017, in cooperation with the Ukrainian counterparts, DoD plans to complete as many as four CBR projects aimed at enhancing disease surveillance, detection, diagnostics, and reporting capabilities. Finally, DoD will continue to support participation of the Ukrainian scientists in the international conferences and workshops, thereby encouraging exchange of best practices between the Ukrainian and international scientific communities, which is expected to lead to improved transparency.

Description of Activities Carried Out in FY 2012: DoD completed construction, commissioning, and Transfer-of-Custody of three MOH DLs at Vinnitsa, Zakarpatye, and Lviv; initiated design and construction work at the three remaining MOH DSDDR DL sites in Kharkiv, Kherson, and Ternopil; continued to provide training and sustainment support at all completed

DSDDR sites; conducted successful Initial Operational Capability Operational Demonstration of the MOH DSDDR network; provided Response Vehicles and associated training to 28 MOH sites; provided biosafety cabinets and associated training to 18 lower level labs; initiated design and construction work at four veterinary DLs. CBEP's project in Ukraine provided 27 classes resulting in over 22,000 student contact hours.

CBEP obtained full approval and Government of Ukraine concurrence for three CBR projects: *Ecological-Epidemiological Evaluation of Prevalence of Natural Focal Infections Caused by Rickettsia Spp. and Coxiella Burnetii in Different Landscape Zones of Ukraine* (UP-1); *Incorporating Geographic Information Systems, Remote Sensing, and Laboratory Diagnostics into Human and Veterinary Disease Surveillance for Tularemia and Anthrax in Ukraine* (UP-2), and *Epidemiologic Algorithms and Molecular Approaches for Differential Diagnosis of Severe Febrile Illness of Unknown Etiology in Ukraine* (UP-3). UP-2 is under way. UP-1 and UP-3 are delayed because of the continued refusal of the Government of Ukraine to consolidate the three select agents currently held at LRIEH to the BSL-3 CRL in Odessa as agreed upon in the Program's bilaterally signed CONOPS in 2009. DoD also approved two additional research projects, *Development and use of the express method for avian influenza virus diagnostics based on the reverse transcription-loop-mediated isothermal amplification* and *"Analysis of the threat of spread of African swine fever and classical swine fever in wild boar populations in Ukraine,"* and approved Phase I of the research project, *Implementation of cell culture and nucleic acid sequencing capabilities at the Ukrainian Research Anti-Plague Institute in order to foster and improve viral diagnostics*. CBEP sponsored scientists from Ukraine

Ukraine (UP-2), and *Epidemiologic Algorithms and Molecular Approaches for Differential Diagnosis of Severe Febrile Illness of Unknown Etiology in Ukraine* (UP-3). UP-2 is under way. UP-1 and UP-3 are delayed because of the continued refusal of the Government of Ukraine to consolidate the three select agents currently held at LRIEH to the BSL-3 CRL in Odessa as agreed upon in the Program's bilaterally signed CONOPS in 2009. DoD also approved two additional research projects, *Development and use of the express method for avian influenza virus diagnostics based on the reverse transcription-loop-mediated isothermal amplification* and *"Analysis of the threat of spread of African swine fever and classical swine fever in wild boar populations in Ukraine,"* and approved Phase I of the research project, *Implementation of cell culture and nucleic acid sequencing capabilities at the Ukrainian Research Anti-Plague Institute in order to foster and improve viral diagnostics*. CBEP sponsored scientists from Ukraine shared their work at several conferences in FY 2012.

Although no formal A&E assessments took place in Ukraine in FY 2012, a number of evaluations and site visits occurred at the completed MOH sites in Lviv, Vinnitsa, and Zakarpatye as well as the CRL at URAPI in Odessa and the Central Sanitary and Epidemiological Station in Kyiv. During these trips, CBEP assessed and validated laboratory facilities, DoD-funded equipment, materials, and technology as well as BS&S plans and procedures, laboratory operation, and laboratory staff training records.

CBEP Ukraine met 61 percent of its planned objectives for FY 2012. It did not meet 100 percent due to the continued refusal of the Government of Ukraine to consolidate its select agent collection at LRIEH. This prevented the initiation of two CBR projects and cancelled planned training and conference participation. Additionally, EIDSS implementation for the Ministry of Health is stalled due to delays in the Government of Ukraine certification process and the State Veterinary Service's and National Academy of Agrarian Science's decision to use their own electronic system for disease reporting. This is included on the CBEP FSU metric

Agreement Between the Department of Defense of the United States of America and the Ministry of Economy of Ukraine on the Provision of Assistance to Ukraine in Establishing an Export Control System in Order to Prevent the Proliferation from Ukraine of Weapons of Mass Destruction, dated October 22, 2001, as amended March 26, 2004, June 27, 2005, September 12, 2006, August 17, 2007, April 16, 2008, and July 9, 2009 **(Export Control Implementing Agreement)**

Agreement between the Department of Defense of the United States of America and the Ministry of Health of Ukraine Concerning Cooperation in the Area of Prevention of Proliferation of Technology, Pathogens and Expertise that Could Be Used in the Development of Biological Weapons, dated August 29, 2005, as amended September 4, 2008 **(Biological Threat Reduction Implementing Agreement – Ukraine)**

Kenya:

Completed: Central Veterinary Lab (Nairobi)
Ongoing: DL at KEMRI (Nairobi)

Russia:

Completed: None.
Ongoing: BS&S renovations at the Pokrov Biologics plant in Pokrov; the All-Russia Research Institute for Animal Health in Vladimir

Ukraine:

Completed: MOH DLs at: Dnipropetrovsk, Zakarpatye, and Lviv
Ongoing: MOH DLs at Kharkiv, Kherson, and Ternopil; MOA DLs at Dnipropetrovsk, Luhansk, and Lviv; and Institute of Veterinary Medicine Training Laboratory

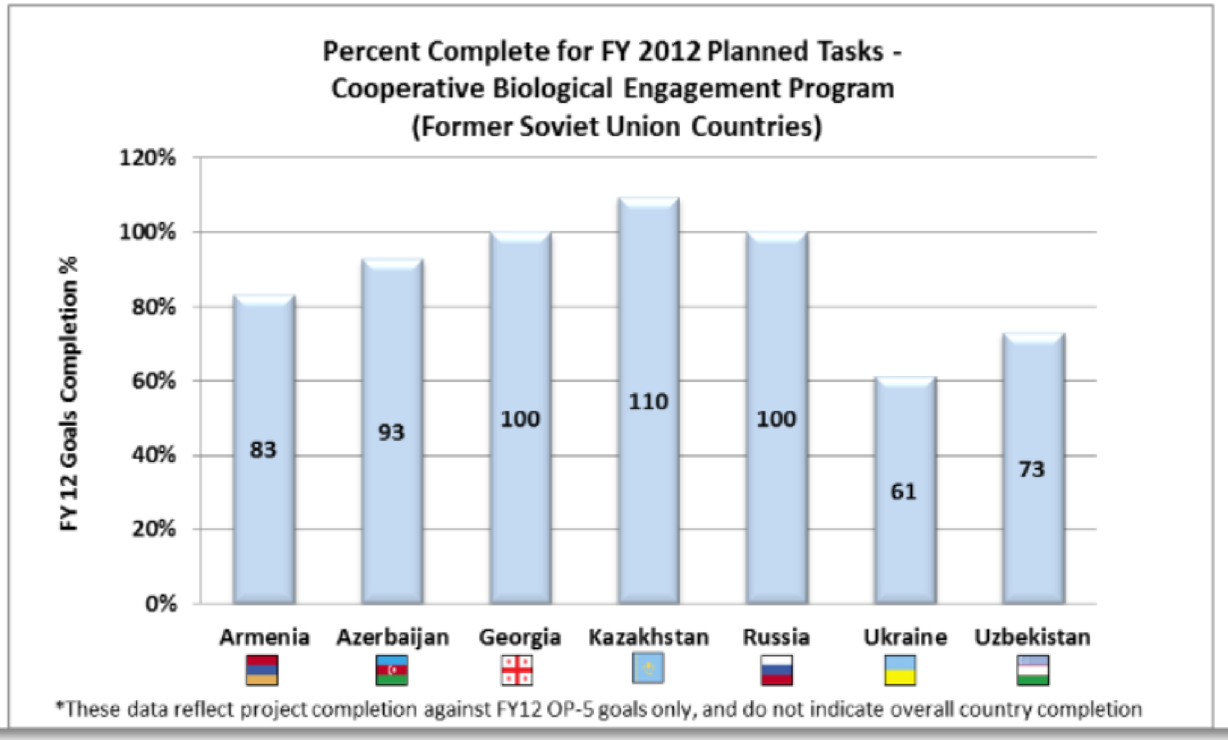
Proliferation Prevention – Azerbaijan and Ukraine

PPP did not perform any CTR Program-funded facility construction this year; therefore, there is no requirement for facility certifications.

2.4. Cooperative Biological Engagement Program (CBEP)

CBEP completed the following percentage of FY 2012 planned tasks with FSU partners: 83 percent with Armenia; 93 percent with Azerbaijan; 100 percent with Georgia; 110 percent with Kazakhstan; 100 percent with Russia; 61 percent with Ukraine; and 73 percent with Uzbekistan. A delay in identifying the first two of four regional laboratories to support disease outbreak reporting was the primary contributor to the score for Armenia. Delays in completing planned training to improve disease identification resulted in the score for Azerbaijan. In Georgia, all activities planned for FY 2012 were completed. Initiating more research projects than planned resulted in Kazakhstan's score above 100 percent. Although CBEP's partnership is limited with Russia, all activities planned for FY 2012 were completed. CBEP had a very robust program planned with Ukraine, but a delay in consolidation of three human pathogens into the Central Reference Laboratory led to a stop of work on planned research and training; there were also delays in completing construction of four regional laboratories and in beginning construction of the Veterinary Central Reference Laboratory. In Uzbekistan, fewer trainings than planned and lack of host country cooperation with the electronics reporting system installation resulted in a lower completion of FY 2012 planned CBEP activities.

Table 9: CBEP – FSU Planned Tasks Achieved in FY 2012



Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines

Paul-Henri Lambert [a], Donna M. Ambrosino [b], Svein R. Andersen [c], Ralph S. Baric [d], Steven B. Black [e], Robert T. Chen [e], Cornelia L. Dekker [e,*], Arnaud M. Didierlaurent [a], Barney S. Graham [g], Samantha D. Martin [h], Deborah C. Molrine [i], Stanley Perlman [j], Philip A. Picard-Fraser [k], Andrew J. Pollard [l], Chuan Qin [f], Kanta Subbarao [m], Jakob P. Cramer [n]

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ABSTRACT

A novel coronavirus (CoV), Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in late 2019 in Wuhan, China and has since spread as a global pandemic. Safe and effective vaccines are thus urgently needed to reduce the significant morbidity and mortality of Coronavirus Disease 2019 (COVID-19) disease and ease the major economic impact. There has been an unprecedented rapid response by vaccine developers with now over one hundred vaccine candidates in development and at least six having reached clinical trials. However, a major challenge during rapid development is to avoid safety issues both by thoughtful vaccine design and by thorough evaluation in a timely manner. A syndrome of "disease enhancement" has been reported in the past for a few viral vaccines where those immunized suffered increased severity or death when they later encountered the virus or were found to have an increased frequency of infection. Animal models allowed scientists to determine the underlying mechanism for the former in the case of Respiratory syncytial virus (RSV) vaccine and have been utilized to design and screen new RSV vaccine candidates. Because some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models, this is a particular concern for SARS-CoV-2 vaccines. To address this challenge, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration (BC) Safety Platform for Emergency vACcines (SPEAC) convened a scientific working meeting on March 12 and 13, 2020 of experts in the field of vaccine immunology and coronaviruses to consider what vaccine designs could reduce safety concerns

Abbreviations: ACE2, Angiotensin-converting enzyme 2; ADE, Antibody disease enhancement; ARDS, Acute respiratory distress syndrome; B/HPIV3, Bovine/human parainfluenza virus type 3; BC, Brighton Collaboration; BPL, β-Propiolactone; BtCoV, Bat coronavirus; CEPI, Coalition for Epidemic Preparedness Innovations; CNS, Central nervous system; COVID-19, Coronavirus Disease 2019; CRISPR, Clustered regularly interspaced short palindromic repeats; DNA, Deoxyribonucleic acid; DPP4, Dipeptidyl peptidase-4; hACE2, Human ACE2 receptor; HBs, Hepatitis B surface antigen; hDPP4, Human DPP4; IHC, Immunohistochemistry; MERS CoV, Middle East respiratory syndrome coronavirus; mRNA, Messenger RNA; MVA, Modified Vaccinia Virus Ankara; NHP, Non-human primate; Non-SPF, Non-specific pathogen free; NTD, N terminal domain; RAG1, Recombination activating gene 1; RBD, Receptor binding domain; rMVA, Recombinant modified vaccinia virus Ankara; RNA, Ribonucleic acid; RSV, Respiratory syncytial virus; SARS-CoV-1, Severe acute respiratory syndrome coronavirus 1; SARS-CoV-2, Severe acute respiratory syndrome coronavirus 2; SPEAC, Safety Platform for Emergency vACcines; TCR, T-cell receptor; Tg, Transgenic; Th1, T-helper cell type 1; Th2, T-helper cell type 2; VSV, Vesicular stomatitis virus; WHO, World Health Organization.

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1. Introduction

Since the identification of a novel coronavirus, SARS-CoV-2, as the cause of pneumonia in patients from Wuhan China, a pandemic has erupted, resulting in enormous health care, social and economic disruption to our global society [1]. As of May 17, 2020 there have been 4,708,415 cases and 314,950 deaths worldwide [2]. In rapid response to the pandemic, academic and industry scientists from around the world have initiated efforts to develop vaccines and therapeutics for disease prevention and patient management. The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership between public, private, philanthropic, and civil organizations, is funding work to develop SARS-CoV-2 vaccines using a variety of technology platforms. Several vaccine candidates are already in Phase 1 studies with others likely to enter the clinic in the next few months [3].

One of the challenges facing rapid vaccine development for SARS-CoV-2 is the need to adequately assure the safety of these vaccines. One such safety concern is disease enhancement syndrome that occurred in the 1960s with inactivated RSV and measles vaccines. Vaccine-mediated disease enhancement is characterized by a vaccine that results in increased disease severity if the subject is later infected by the natural virus. During early trials with inactivated RSV vaccine, the vaccine did not prevent infection, 80% of those infected required hospitalization and two children died [4]. Lung pathology in patients showed an unexpected inflammatory response with both neutrophils and eosinophils, evidence of immune complex formation and complement activation in small airways [5]. Scientists later learned that the vaccine caused a similar disease enhancement in animals characterized by immunopathology and a T helper cell type 2 (Th2) biased response and antibody responses with poor neutralizing activity [6–8]. Since that time, the animal models have been relied upon to predict safety for new RSV vaccines that are developed. Of note, the pathogenesis of RSV disease enhancement is distinct from antibody disease enhancement (ADE) which occurs for macrophage tropic viruses, demonstrated most notably for Dengue in humans and the coronavirus feline infectious peritonitis virus in cats, and is directly caused by non-neutralizing or sub-neutralizing antibodies leading to more efficient viral uptake via Fcγ receptor binding [9].

Since pathology consistent with the RSV vaccine enhanced disease (and perhaps ADE) has been demonstrated for some SARS-CoV-1 vaccine candidates in animal models, there is also a concern that a similar syndrome could occur in humans immunized with SARS-CoV-2 candidate vaccines. Therefore, CEPI and the Brighton Collaboration Safety Platform for Emergency vACcines (SPEAC) convened a scientific working meeting https://brightoncollaboration.us/brighton-collaboration-cepi-covid-19-web-conference/) on March 12 and 13, 2020 of experts in the field of vaccine immunology and coronaviruses to discuss current knowledge that could form the basis for the assessment of the risk of enhanced disease during SARS-CoV-2 vaccine development. This consensus report presents considerations for vaccine developers and can serve as a guide for the development and testing of vaccine candidates to avoid these safety concerns. Ultimately, the door to clinical trials is controlled by regulators in the context of the risk/benefit for the entire dataset provided by developers and within the local trial context.

2. Animal models of SARS-CoV-1 and MERS CoV

Dr. Kanta Subbarao, director of the WHO Collaborating Centre for Reference and Research on Influenza and Professor in the Department of Microbiology and Immunology at the University of Melbourne, and Dr. Stanley Perlman, Professor in the Departments of Microbiology and Immunology and Pediatrics at the University of Iowa, both reviewed their work and that of others in animal models developed for SARS-CoV-1 and MERS-CoV. The lessons from these models can inform the development priorities for useful SARS-CoV-2 animal models to address both efficacy and safety.

In inbred mouse strains, SARS-CoV-1 replicates efficiently in the respiratory tract and can cause pneumonitis, but clinical signs and pneumonia were only observed in old BALB/c mice [10]. Subsequent passage of SARS-CoV-1 through mouse lungs resulted in the isolation of virus that caused severe disease in both young and old mice [11,12]. This virus was used in many subsequent studies. Ferret models of SARS-CoV-1 also demonstrate virus replication in respiratory tracts with induction of a neutralizing antibody response but also demonstrated little evidence of clinical disease [13]. Hamsters, in contrast to mice and ferrets, demonstrate high levels of viral replication, develop pneumonitis, and can be shown to have clinical signs of disease [14]. Following the identification of human ACE2 as the receptor for SARS-CoV-1, transgenic murine models expressing human ACE2 receptor (hACE2) were developed and shown to develop mild pulmonary disease. Of note, these mice also developed lethal viral encephalitis, attributed to viral spread through the olfactory nerve, despite the relative scarcity of hACE2 expression in the brain which may have relevance to SARS-CoV-2 disease [15].

Efficacy of several SARS-CoV-1 vaccines was evaluated in these models with spike (S) protein based vaccines demonstrating neutralizing antibody and protection against pulmonary replication of the challenge virus in mice and hamsters [16]. For DNA vaccine studies, it was shown that candidate vaccines encoding the S protein conferred antibody mediated protection from challenge in mice and that vaccines encoding the N protein induced humoral and cellular immunity [17,18]. For vectored vaccines expressing SARS-CoV-1 proteins, it was shown that viral proteins were expressed in mice, ferrets, and hamsters. In these studies, neutralizing antibodies were elicited by B/HPIV3, VSV, rabies, MVA and adeno viruses expressing S protein, that protected against SARS-CoV-1 replication in lungs of challenged animals. However, one MVA vaccine expressing the S-protein did not protect against infection [16].

In contrast to SARS-CoV-1, inbred mice were found to be resistant to MERS-CoV, thus infection was studied by creating models that expressed the MERS receptor, human DPP4 (hDPP4). Ad5-hDPP4 transduced mice could be infected with MERS virus but infection was associated with minimal clinical disease except in immunocompromised mice that developed weight loss after infection. Of note, hDPP4-transgenic mice developed lethal viral encephalitis with concurrent inflammatory changes on histopathological examination of the lung, similar to hACE2-Tg mice with SARS-CoV-1. Subsequently, investigators developed mice "knocked-in" for expression of hDPP4 and after virus passage in these mice, identified mouse-adapted MERS strains that caused

more severe disease and increased histopathology with more pulmonary edema than those infected with the original MERS strain [19]. Importantly, mice without functional T cells, such as RAG1-/- and TCR alpha-/-, had delayed viral clearance whereas mice that could not produce antibodies, muMT mice, did not show delay in clearance. Similar models were developed by CRISPR/Cas9 mutagenesis of two residues in the mouse ACE2 molecule, followed by mouse adaptation with serial passage, leading to an ARDS model of lethal infection [20,21]. Taken together this evidence supports the notion that T cells are important in viral clearance for MERS [22].

Non-human primate (NHP) models have also been established for both SARS-CoV-1 and MERS-CoV. There was evidence of upper respiratory and lower respiratory tract SARS-CoV-1 replication in African green monkeys to a greater extent than in cynomolgus macaques, and least in rhesus macaques, with little evidence of clinical disease in all three species [23]. Of note, consistent with findings in older humans and mice, increased pathology has been documented in aged cynomolgus macaques with SARS-CoV-1 wild type infection [24]. There is some controversy on the disease severity in the MERS models with different groups seeing different levels of pathology. This has not been resolved [25,26].

3. Enhanced disease following SARS-CoV-1 vaccines

Both vaccine efficacy and safety have been studied in animal models with many SARS-CoV-1 candidate vaccines. The group of experts discussed how the vaccine models were utilized to characterize the response of specific vaccines and to examine both disease enhancement and antibody dependent enhancement (ADE) signals.

There is evidence for disease enhancement in vaccinated animals after challenge with live virus in multiple studies with SARS–CoV-1 vaccine candidates as summarized in Table 1. We are limiting our comments in this report to data in animal models and not discussing *in vitro* data except to mention that there is some evidence of ADE in human primary monocytes [27,28]. Different animal models exhibit different pulmonary pathology but generally are characterized by cellular infiltrates including eosinophils. In this summary, we provide an overview of the consensus opinion on vaccine related outcomes in animal models that were of concern for risk of disease enhancement and could guide assessments of SARS-CoV-2 vaccine candidates.

In murine models, evidence for vaccine related disease enhancement has been demonstrated for inactivated whole vaccine (with and without alum), vectored vaccine expressing N protein (but not seen with vectored vaccine expressing S protein in same report), a replicon particle platform expressing S protein, and a vectored vaccine expressing S proteins. In general, the pathology described included pulmonary infiltrates often with eosinophils observed. Th2 dominant responses were documented in some reports by expression of Th2 driven cytokines [29–33]. In a ferret model, hepatitis was demonstrated in animals vaccinated with a recombinant modified vaccinia virus Ankara vaccine expressing S protein and then challenged with virus [34] although questions have been raised about this study [35].

Of note, mouse models have also shown evidence of enhanced disease for inactivated and recombinant adenovirus 5-based MERS-CoV vaccine [36,37].

Non-human primate models have also produced evidence of enhanced disease after SARS-CoV-1 vaccine immunization. Chinese macaques immunized with a modified vaccinia virus expressing S protein then challenged with SARS-CoV-1 did not develop clinical disease, but histopathology showed lung injury. This injury was characterized by decreased wound healing, and increased pro-inflammatory macrophages expressing IL-6, IL-8, and CCL2 [38]. This report also demonstrated that passively administered anti-S antibody was associated with lung pathology after challenge with the live virus although the mechanism may not be through Fc receptor and thus not classic "ADE". Of note, a second report similarly demonstrates the effect with certain anti-S antibody preparations and without Fc involvement [39,40]. The relevance of these reports remains unclear as there are multiple studies with administration of neutralizing monoclonal antibodies to different models that did not induce disease enhancement. Other investigators have reported absence of disease enhancement in both hamsters and monkeys immunized with a whole inactivated vaccine although these models differed in a number of ways, most notably by the use of BPL (β-Propiolactone) instead of formalin for inactivation of the virus [41,42]. Finally, we note that there has not been an agreed upon positive control applied in these animal studies and thus interpretations are hampered.

4. SARS-CoV-2 murine and NHP models newly developed

Animal models with SARS-CoV-2 are being rapidly developed by multiple research groups. Dr. Qin Chuan, Professor and Director

Table 1
Evidence of enhanced disease in SARS-CoV-1 vaccine candidates.

Animal Model	Vaccine	Adjuvant	Immunopathology	Reference
Murine[1]	VEE Replicon Particles expressing N protein	–	YES	Deming 2006
Murine[2]	Recombinant Vaccinia virus expressing N protein	–	YES	Yasui 2008
Murine[3]	Inactivated Whole Virus	Alum	YES	Bolles 2011
		–	YES	
Murine[4]	Replicon Particles expressing S protein	–	YES	Sheahan 2011
Murine[5]	Inactivated Whole Virus and S protein vaccines	Alum	YES	Tseng 2012
		–	YES	
Ferret[6]	Recombinant Modified Vaccinia Virus Ankara (rMVA) expressing S protein	–	YES[!]	Weingartl 2004
NHP[7]	Modified Vaccinia Ankara (MVA) virus encoding full-length S protein	–	YES	Liu 2019
	Passive anti-S sera	N/A	YES	
NHP[7]	Inactivated Whole Virus	–	YES	Wang 2016/2020
	Passive Human SARS Antiserum	N/A	YES	

[1] Young and senescent female BALB/c mice.
[2] BALB/c mice.
[3] Aged BALB/c mice.
[4] Young and aged BALB/c mice.
[5] Female BALB/c mice.
[6] *Mustela putorius furo*, castrated males.
[7] Chinese rhesus macaque.
[!] Acute hepatitis.

of the Institute of Laboratory Animal Science, Comparative Medicine Center of the Peking Union Medical College presented data on SARS-CoV-2 infection in both transgenic mice and rhesus macaque models.

Human ACE2 transgenic mice (hACE2 Tg) aged 4–6 weeks and 6–11 months of age were studied and hACE2 expression was observed in lung, heart, kidney and intestinal tissues. Following intranasal inoculation with SARS-CoV-2, weight loss was observed, and viral RNA was detected in the lungs as well as in the intestine [43].

Gross pathology demonstrated swollen and enlarged lungs with moderate interstitial pneumonia. Histological studies documented an accumulation of inflammatory cells including monocytes and lymphocytes in alveolar interstitium, with thickening of alveolar walls. SARS-CoV-2 S protein was detected by IHC in alveolar macrophages and epithelia [43].

NHP were also infected with SARS-CoV-2 with 3 rhesus macaques aged 3–4 years inoculated intratracheally and although no fever was observed, weight loss and asthenia were seen on multiple days. Viral RNA was detected from nasal and throat swabs and to a lesser degree in anal specimens, peaking on days 3 to 7 and lasting until day 11 post infection. One animal was euthanized on day 7 for necropsy and viral RNA was detected in multiple organs including CNS, skeletal muscle and heart. For the two surviving rhesus macaques, positive neutralization titers were documented by day 11 post infection. There was radiographic evidence of multiple ground glass opacities in the lungs on days 3, 5 and 7 post infection. Microscopically the lung lesions represented an acute interstitial pneumonia characterized by mild to moderate thickening of alveolar septum, increased number of macrophages, degeneration of pneumocytes and an inflammatory cell infiltration. Presence of viral antigen was confirmed, predominately in alveolar monocytes and macrophages [44]. Analysis of blood samples showed a decline in counts of total white blood cells, lymphocytes and monocytes with no observed changes in percentages. A decrease in both CD3 + CD4 + and CD3 + CD8 + T-cell counts was observed. Importantly, these hematological findings are similar to those seen in SARS-CoV-2 infected patients.

This model could serve as a critical tool for detailed studies of pathogenesis and the evaluation of intervention strategies including vaccines. Of note, following the meeting another group has confirmed SARS-CoV-2 infection in rhesus macaques with viral antigen detected in type I and type II pneumocytes and diffuse pulmonary alveolar damage noted [45]. Experts agreed that these models and others under development should be utilized to evaluate vaccine candidates for any evidence of disease enhancement as specified in later sections.

5. COVID-19 vaccine design considerations for efficacy and safety

5.1. Structure and function of S glycoproteins in coronavirus

Design of safe and effective COVID-19 vaccines can be informed by knowledge of previous coronavirus vaccine development activities and shared elements of viral pathogenesis for non-coronaviruses such as RSV. Specific epitope targets for potent neutralizing antibody, platforms for inducing both neutralizing antibody and effective T cell responses, and adjuvants for improving immunogenicity were presented at the conference. We review first the structure and function of the major target of COVID-19 vaccines, spike (S) glycoprotein.

Ralph Baric PhD, Professor in the Department of Epidemiology at the University of North Carolina Chapel Hill School of Medicine presented a review of the structure and function of coronavirus (CoV) S glycoprotein highlighting priorities for the development of vaccine and immune therapeutics. There is a long history of emerging CoVs with acceleration of cross-species movement and emergence of highly pathological strains in the last 16 years, including SARS-CoV-1, MERS-CoV, and SARS-CoV-2, and this trend is likely to increase in the future. Phylogenetic relationships within CoVs have been established, and Group 2B includes SARS-CoV-1 and SARS-like CoVs including SARS-CoV-2, BtCoV WIV1 and BtCoV SHC014. Similarly, Group 2C are MERS-like CoVs which are also poised for human emergence. Within Group 2B, known SARS-like CoVs are divided into high or low pre-epidemic potential. High risk features include use of ACE2 for cell entry, growth in primary human airway cells, causing ARDS, causing age-related disease severity, and escape from existing immune therapeutics. Drivers of CoV evolution include the high mutation rate of the RNA-dependent RNA polymerase paired with the regulated fidelity complex. CoVs also demonstrate high rates of RNA recombination as during mixed infection up to 25% of progeny are recombinant, and modular evolution allows CoVs to swap whole genes or portions of key proteins between strains. The S protein itself, which regulates host range, tissue tropism, and transmissibility, can tolerate a high mutation rate while retaining its function.

The organization of the SARS-CoV-2 genome has been elucidated and SARS-CoV-2, like SARS-CoV-1, has been shown to use hACE2 for cell entry. Group 2B viruses have fourteen contact interfaces between their S protein and ACE2. Variation across the interface sites can facilitate orthologous species ACE2 receptor usage, since as few as seven interface sites are needed for entry. The prefusion structure of the S glycoprotein has three major antigenic domains, receptor binding domain (RBD), N terminal domain (NTD), and S2. Epitopes on SARS-CoV-1 RBD have been identified as targets for neutralizing antibodies. Analyzing the variations and conserved regions in the S protein of Group 2B SARS-like CoVs, shows conserved sites on the S2 region that could be targeted in broad-based therapeutics against multiple CoVs.

Dr. Baric stressed that there is a large reservoir of SARS-like and MERS-like CoVs poised for emergence in humans. Two priorities are immediate vaccine candidates specific for SARS-CoV-2 and development of broad-based vaccines protective against antigenically distinct CoVs destined to emerge in the future. Key priorities for the development of a SARS-CoV-2 vaccine include characterization the SARS-CoV-2 neutralizing epitope map, identification of broadly cross-reactive neutralizing epitopes, identification of putative enhancing epitopes that might potentiate disease *in vivo*, identification of key T cell epitopes across outbred populations, and determination of correlates of protective immunity.

5.2. Preserving neutralization sensitive epitopes on spike proteins

Barney Graham, MD PhD, Deputy Director of the NIH Vaccine Research Center presented data on the immunogenicity and neutralizing efficacy of truncated spike (S) antigens, with a focus on SARS-CoV-2. Class I fusion proteins (such as S protein) are common among enveloped viruses including RSV, parainfluenza viruses, and coronaviruses and have been successfully stabilized in their prefusion conformations. This approach has been shown to preserve neutralization-sensitive epitopes, avoid antibodies that are non-neutralizing, and improve expression in transfected cells, thus aiding in manufacturing and immunogenicity of gene-based vectors. The S proteins of SARS-CoV-1 and MERS-CoV have both been successfully stabilized by introducing two proline residues to the top of the central helix, preventing heptad assembly and stabilizing the S2 region and the entire S protein as a result (Fig. 1) [46].

The SARS-CoV-2 S protein structure was solved shortly after its emergence and shows similar structure and mobility as the SARS-CoV-1 S [47]. The timing from first knowledge of SARS-CoV-2 to the

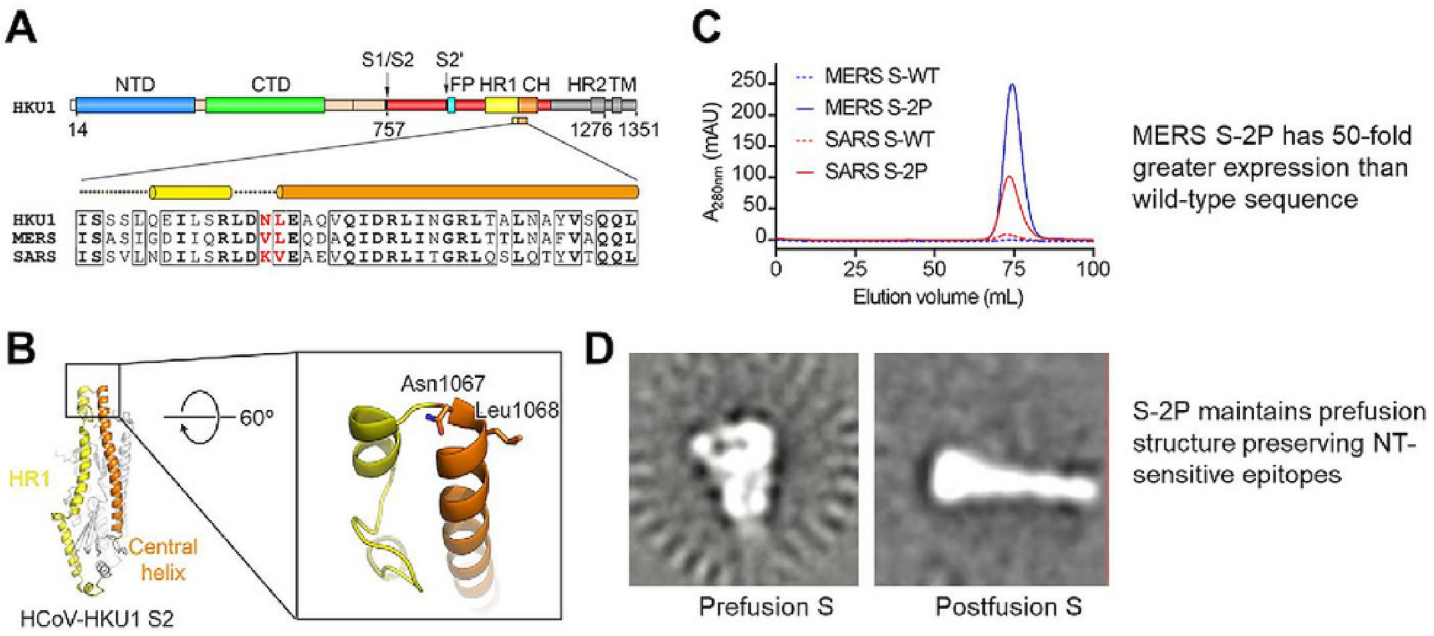


Fig. 1. 2P mutation stabilizes MERS and SARS CoV S; improves expression, prefusion structure, and immunogenicity.

beginning of the Phase 1 study was a remarkable sixty-five days. The advantages of mRNA vaccines include ability to create a highly precise type of protein to elicit the correct antibodies, to elicit T cell responses that are Th1 predominant, and the rapidity of manufacturing. Of course, disadvantages include the novel nature of both mRNA and DNA vaccines without any licensed vaccine with either technology to date and lack of experience for mass production. Therefore, multiple platforms for SARS-CoV-2 are under development that mitigate against some of the potential disadvantages of nucleic acid vaccines.

6. Effects of adjuvants on immune response and implications for COVID-19 vaccines

Although mRNA and DNA vaccines elicit T cell responses without adjuvants, adjuvants may be important for subunit and whole cell inactivated vaccines to increase their immunogenicity and drive an immune response that could limit the risk of disease enhancement. Multiple SARS-CoV-2 vaccines are in development including vectored vaccines, whole cell inactivated vaccines, and recombinant protein vaccines. The experts discussed how the choice of adjuvants will be important for both efficacy and safety with these platforms.

Dr. Arnaud Didierlaurent from the Centre of Vaccinology at the University of Geneva presented background on the effects of different adjuvants on animal and human immune responses. Several adjuvants are now being used in commercial vaccines or are in clinical development [48]. Oil-in-water emulsions such as MF59 or AS03 have been shown to increase the breadth of the antibody repertoire, binding affinity and affinity maturation when compared to unadjuvanted vaccines [49,50] In human studies with influenza vaccines, H5N1 vaccine adjuvanted with MF59 (squalene-based emulsion) increased the levels of H5-specific antibody for subclasses IgG1 and IgG3 and the binding to FcγR2 but not to FcγR3 when compared to alum adjuvanted vaccines. This demonstrates that the use of an adjuvant can skew the functionality profile of antigen-specific antibodies, with the potential to activate different innate effectors based on their FcγR expression [51]. Use of squalene-based emulsion vaccines for influenza have also been shown to increase CD4 + T cell response frequencies and cross-reactivity. Even if pre-existing cross-reactive antibodies are present prior to immunization, such adjuvants could activate naïve B cells and promote the adaptability of memory B cells [52–55].

In addition to antibodies, adjuvants can promote cellular responses. Human malaria challenge studies provided early evidence that the choice of adjuvants (combined with the malaria antigen RTS,S) was critical in achieving optimal protection and highlighted the importance of cellular response [56]. More recently, studies with Hepatitis B Surface Antigen (HBs) vaccine adjuvanted with AS01, AS03, AS04 or alum showed that vaccines formulated with AS01 and AS03 induced the highest antibody levels while AS01 promoted best HBs-specific CD4 T cell response [57]. These differences were associated with the magnitude of the initial inflammatory response triggered by the different adjuvanted formulations [57,58]. Interestingly, although the level of CD4 T cell response was lower in the alum group compared to the AS01 group, both adjuvants led to similar memory subset profiles and cytokine production profiles (polyfunctionality) and neither induced Th2 cytokines nor a CD8 induced response upon peptide restimulation. This indicates that use of alum may not necessarily lead to Th2 skewing in humans. Recently a number of systems biology studies have revealed that specific early signatures (e.g., interferon-dependent pathways) induced by adjuvanted vaccines are often associated with protective responses [59] but the impact of these early signals on functional features of antibodies and the quality of T cell response are not well established yet.

Although adjuvant selection is best performed in early clinical studies, animal models could be useful in determining the immune profile of adjuvanted vaccines. NHP models are well-established to assess immune responses to vaccination and elicit immune responses in closer parallel to humans than mice. For example, in non-human primates, adjuvant choice affects antibody half-life, antibody glycosylation and antibody binding to FcγRs, indicating effects on both antibody quality and function, like what is observed in humans [60]. When adeno-based vectored vaccines are given to humans or NHPs, both groups develop similar antibody function profiles. Additionally, NHPs and humans tend to show similarities in terms of "ranking" of adjuvants and innate immune pathways triggered by adjuvants. Overall, NHPs could be utilized to evaluate COVID-19 vaccine candidates with and without adjuvants and guide in the selection of vaccines that elicit desired attributes that could reduce the risk of vaccine-mediated enhanced disease.

Given the unprecedented demand for an effective vaccine, the use of adjuvants may be critical for subunit vaccines in providing antigen-dose sparing, increased immunogenicity, breadth and duration of response, potentially eliciting cross-protection against new CoV strains and minimizing the risk of enhanced disease.

7. Consensus considerations on the assessment of the risk of disease enhancement with COVID-19 Vaccines:

Following the presentations, attendees participated in discussion of the suggested consensus statements and all attendees were asked to comment on the draft statements available online. These comments were reviewed and discussed again on the second day of the meeting and resulted in the summary consensus statement that follows.

Murine models for assessment of vaccine-related disease enhancement

- SARS-CoV-2 has a low affinity for murine ACE2 receptor and murine models will require the use of hACE2 transgenic mice, preferably with a 'knock-in' approach. Preliminary data indicate the possibility of infecting hACE2 transgenic mice with demonstration of viral replication and mild lung lesions. Mouse adaptation of SARS-CoV-2, as done with SARS-CoV-1, will likely be required to obtain a virus that causes more severe disease in mice. Models that develop acute lung injury with some lethality and that mimic the human condition will be important for evaluating vaccine safety.
- Previous studies from SARS-CoV-1 and MERS-CoV indicated that some vaccines, especially those using whole inactivated virus, could enhance the disease induced in mice challenged with SARS-CoV-1 or MERS-CoV. The lung lesions were highly inflammatory, with a dominance of eosinophil infiltration and occurred in animals despite presence of a neutralizing antibody response and reduced challenge virus replication in the lungs. Such studies have not yet been completed for SARS-CoV2.
- In mice, this immunopathology was considered a consequence of a dominant Th2 type response to the vaccine antigens. It was not seen after including adjuvants (e.g. CpG) in the vaccine or other vaccine formulations known to drive immune responses towards Th1. The timing of challenge after vaccination may be critical. It would be of major interest to explore the outcome following challenge at later timepoints when antibodies are significantly decaying.
- One should be aware of the potential confounding effect of cell-culture excipients in the vaccine and challenge strain material. It is known that impurities such as fetal calf serum in the preclinical vaccine preparation may induce eosinophil influx in any mouse model if the challenge strain also contains the same excipients.
- In these models, characterization of the immune response to the candidate vaccine (e.g., IgG isotypes, Th2 markers) may have some predictive value.
- Other small animal models which can be infected by SARS-CoV-2 can be considered (e.g. ferret, hamster). Development of small animal models of severe disease will also inform studies of vaccine-enhanced disease.

Non-human primate models for assessment of vaccine-mediated enhanced disease

- Non-human primates (NHP) are of primary interest in view of their ACE2 homology with hACE2. Preliminary studies indicate the possibility of inducing some COVID-19 lung pathological features after infection, without clinical signs, in Rhesus macaques. African Green monkeys may be more susceptible to COVID-19, but the model suffers from some limitations (e.g. access, genetic polymorphism).
- Previous studies with SARS candidate vaccines have suggested a risk of enhanced pathology in NHPs after viral challenge. Eosinophilic infiltrates were not prominent. The mechanism is still incompletely defined but there is evidence for a role of non-neutralizing antibodies. Non- or incompletely neutralizing antibodies may contribute to:
  - the formation of pathogenic immune complexes and
  - Fc-mediated viral capture by monocytes/macrophages that may favor excessive T-cell activation and inflammation.
- Enhanced pathology was seen following passive transfer of IgG from immunized NHPs

General considerations on animal models

- Although existing animal models of COVID-19 imperfectly reproduce the human disease, they appear useful for assessing the risk of disease enhancement. Vaccine responses are closer to human responses in NHPs than in mice. Therefore, it is likely that data obtained from NHP studies are more significant. However, there is an urgent need to standardize the NHP model (read-out of disease enhancement, timing of challenge, age) and to include appropriate controls (i.e., a vaccine that induces enhanced pathology and disease) and a sufficient number of animals to be confident of findings in outbred species. It is important to control for potential co-infection, including with other coronaviruses, in all non-SPF models.
- Potential markers of safety in these animal models could include:
  - the relative levels of neutralizing vs non-neutralizing antibodies,
  - antibody affinity,
  - T-cell response profile,
  - quantitative virology in the upper and lower respiratory tract
  - characterization of lung histopathology with immunohistochemistry for viral antigen and immune cell markers.
- Passive transfer in NHPs of human antibodies generated during Phase 1 trials, followed by viral challenge could be considered to assess the risk of disease enhancement.
- Challenge of immunized animals with a closely related heterologous CoV strains may assess the risk of enhancement during future outbreaks.
- In case of disease enhancement, in-depth studies in animal models may give some indications on the mechanism of immunopathology. They can inform human trial designers on the critical immunological risk markers to be monitored in Phase 1 trials.
- Based on previous experience with SARS and other viral diseases, it may be useful to evaluate the risk of disease enhancement for COVID-19 vaccines (particularly those including whole virions or N protein) in an established NHP model before advanced clinical development.

During the Vaccine Design session, the group of Experts suggested that consideration should be given to the following:

- Caution should be observed when developing vaccines to avoid inducing predominant Th2 responses and non-neutralizing antibodies.
- Vaccines inducing strong neutralizing antibodies, predominant Th1 responses and balanced CD4/CD8 and polyfunctional T cell responses are less likely to induce immunopathology.

- Given what will be the unprecedented demand for an effective vaccine, the use of adjuvants may be critical for sub-unit vaccines in providing increased immunogenicity, breadth of response, dose sparing, duration of response, potentially cross-protection against new CoV strains, and possibly minimize the risk of enhanced disease. Preference should be given to Th1-driving adjuvants with an established safety profile in humans.
- Understanding the role cross-reacting antibodies from prior coronavirus infections may have on natural disease caused by SARS-CoV-2 or if they influence the risk of enhanced disease following vaccination may inform vaccine design.
- Data are needed on whether antibody waning could increase the risk of enhanced disease on exposure to virus in the long term.

It was the opinion of the Experts that animal data to support clinical development could address:

- Post-vaccination (neutralizing) antibody responses, and T cell analysis to demonstrate a Th1 response.
- Post-vaccination challenge data from NHPs with careful evaluation for immunopathology and quantitative virology in the animals.
- Small animal data may also provide important supporting evidence of safety, and hamster, ferret and mouse models are likely to be available for developers.
- Where possible, immunopathology experiments with a positive control (e.g., formalin inactivated alum-adjuvanted SARS-CoV-1 or SARS-CoV-2 vaccine) and a mock-immunized negative control will provide best guidance. It was felt that it will be important to establish broadly accepted endpoints and scoring systems to allow comparison of various vaccine candidates. WHO is working on this issue.
- For vaccine constructs likely to induce a predominant Th2 response, the group felt that animal studies should be considered before entering human Phase 1 trials in more than one animal species including NHPs where possible. It was noted that the absence of a Th2 response does not eliminate the risk of enhanced disease.
- For vaccine constructs which are already known to induce neutralizing antibody and Th1 responses, it was the consensus of the group that while Phase 1 studies are cautiously proceeding with careful review of safety data, animal studies run in parallel could provide useful information for the further clinical development
- Suggestive data in animal models should not by default prevent clinical development of vaccine candidates; potential risk should be thoroughly evaluated by developers and regulators on a vaccine product-specific basis.

Regarding Phase 1 clinical trials, it was the opinion of the Experts that:

- Since not all studies that have begun or are about to begin will prescreen to determine preimmunization serostatus of participants, although this shall be determined retrospectively, appropriate baseline blood specimens should be obtained and stored. Because the virus is spreading rapidly, such specimens will allow assessment of the immune response in both seronegative and seropositive persons as both are likely to be vaccinated.
- Level of neutralizing antibodies and determination of the relative ratio of binding to neutralizing antibodies will be important to assess the potential risk of enhanced disease. Also, detection of initial priming that includes CD8 T cells and/or a CD4 Th1 biased response is likely to mitigate the risk of disease enhancement. Determination of memory responses will be useful, particularly if SARS-CoV-2 continues to circulate.
- Consideration should be given to the use of post-vaccination sera from vaccinees which could be used for antibody transfer studies in animals to look for enhanced disease and for evidence of cross-protection against other coronaviruses.
- Monitoring for enhanced disease in immunized participants may require longer follow-up than is usual in Phase 1 trials but need not delay Phase 2 trials.
- Investigators on the call requested frequent updating with both preclinical and evolving clinical data that are being developed by the different academic and industrial developers to help in decision-making about the various vaccine clinical trials. Creation of a central information hub was encouraged for this purpose.
- Participants on the call expressed the need for standardization of protocols, data collection forms, critical assays (including reagents) and biobanking of samples from initial clinical trials to allow future re-assay once standards are agreed to and enable comparison of results across trials

Concluding remarks

- The group of Experts considers that the demonstration of some disease enhancement with any candidate vaccine after viral challenge in animal models should not necessarily represent a no-go signal for deciding whether to progress into early trials in clinical development of a COVID-19 vaccine.
- Continuous monitoring of this risk during clinical trials in an epidemic context will be needed.
- Each observed effect should be discussed by the developers with their regulators who will ultimately define the actual requirements for clinical studies.

The considerations in this document should be interpreted as general scientific remarks based on current knowledge to inform a research agenda that could be beneficial for vaccines in development. These considerations are not of a regulatory nature and cannot in any sense replace the need for proper regulatory consultations on the requirements for vaccines clinical trials. Vaccine developers are therefore encouraged to seek individual scientific advice from regulatory authorities.

Disclaimer

The findings, opinions, conclusions, and assertions contained in this document are those of the individual authors. They do not necessarily represent the official positions of any participant's organization (e.g., government, university, or corporations) and should not be construed to represent any Agency determination or policy.

Declaration of Competing Interest

RB has collaborations with VaxArt, Takeda, Moderna, Eli Lily, and Pfizer. SB is a consultant for GSK on matters unrelated to the topic of this manuscript. CD is a consultant to Medicago on their vaccine programs; her husband owns stock in Dynavax Technologies Corporation. BSG is a named inventor on patent applications related to coronavirus vaccines and monoclonal antibodies. AJP is Chair of UK Dept. Health and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI) and is a member of the WHO's SAGE. AJP is an NIHR Senior Investigator. PL, DA, SRA, RTC, AMD, SDM, DM, SP, PAP, CQ, and KS declare no competing financial interests or personal relationships that could have appeared to influence the work reported in this manuscript.

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All authors attest they meet the ICMJE criteria for authorship.

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Homeland Security

In response to the 2001 anthrax attacks, the President and Congress established the BioWatch Program (BioWatch) in 2003.[1] The program embarked on an aggressive effort to deploy a nationwide system to surveil for aerosolized exposure caused by the intentional release of biological agents. This system was initiated in 30 of the most populous cities within the United States. After the creation of DHS, BioWatch was initially established under the Science and Technology Directorate, and in 2007 was transferred to DHS' Office of Health Affairs. Then, in 2018, BioWatch transferred to DHS' Countering Weapons of Mass Destruction (CWMD) office with a budget averaging $76 million per fiscal year from 2018 to 2020.[2]

EcoHealth Alliance Contract 2016, 2019, 2021, 2022

Dates

Date Signed *(mm/dd/yyyy)* :	10/19/2021
Period of Performance Start Date *(mm/dd/yyyy)* :	09/30/2016
Completion Date *(mm/dd/yyyy)* :	09/29/2019
Est. Ultimate Completion Date *(mm/dd/yyyy)* :	10/14/2022
Solicitation Date *(mm/dd/yyyy)* :	

Amounts

	Current	Total
Action Obligation:	-$31,658.43	$974,297.67
Base And Exercised Options Value:	-$31,658.43	$974,297.67
Base and All Options Value (Total Contract Value):	-$31,658.43	$2,136,843.99
Fee Paid for Use of IDV:	$0.00	

Purchaser Information

Contracting Office Agency ID:	7001	Contracting Office Agency Name:	OFFICE OF PROCUREMENT OPERATIONS
Contracting Office ID:	70RWMD	Contracting Office Name:	CWMD ACQ DIV
Funding Agency ID:	7062	Funding Agency Name:	COUNTERING WEAPONS OF MASS DESTRU
Funding Office ID:	70DWM1	Funding Office Name:	ASST SCTY COUNTERING WPNS OF MASS D
Foreign Funding:	Not Applicable		

Entity Information

FAR 4.1102 Exception: Remove Exception

Unique Entity ID:	TKS7NBB4JDN6	Street:	460 W 34TH ST 17TH FL
Legal Business Name:	ECOHEALTH ALLIANCE INC.	Street2:	
DBAN:		City:	NEW YORK
CAGE Code:	3MMU3	State:	NY Zip: 100012320
		Country:	UNITED STATES
		Phone:	(212) 380-4479
		Fax No:	(212) 380-4465
		Congressional District:	NEW YORK 12

Business Category

Show Details

Organization Type:	CORPORATE TAX EXEMI
State of Incorporation:	MA
Country of Incorporation:	USA

Business Types
✓ Corporate Entity, Tax Exempt
Relationship With Federal Government
✓ All Awards
Organization Factors
✓ Non Profit Organization

Funder: DHS, Countering Weapons of Mass Destruction

What specific research projects has EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction

The search results do not provide specific information on the research projects that EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction. However, according to a news article, the Defense Threat Reduction Agency (DTRA) began awarding funding to EcoHealth Alliance for a work program labeled “Scientific Research – Combating Weapons of Mass Destruction” beginning in fiscal year 2014 [1]. The DTRA describes its mission as “to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks” [1]. The funding from the DTRA was part of the Department of Defense's efforts to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks [1].

1 nypost

what is the role of industry/academia collaboration in CWMD research and prototype work

The Countering Weapons of Mass Destruction (CWMD) Office executes research and prototype work through project teams from a broad-based industry/academia collaboration [1] [2] [3]. The CWMD Consortium is an enterprise through which the Department of Defense CWMD/CBRN community, industry, and academia work collaboratively to develop prototype solutions [1]. CWMD, in collaboration with interagency and private-sector partners, identifies technological trends and advancements relevant to chemical, biological, radiological, and nuclear threats [4]. The Medical CBRN Defense Consortium (MCDC) also executes research and prototype work through project teams from a broad-based industry/academia collaboration [3]. The role of industry/academia collaboration in CWMD research and prototype work is to bring together experts from different fields to develop innovative solutions to detect, deter, and defend against chemical, biological, radiological, and nuclear threats [5]. By working collaboratively,

Project ARGUS Global

Intelligence Technology Innovation Center
ITIC

Global Argus



4 February, 2008

ITIC • ITIC • ITIC •

History

- R&D began in summer 2004.
- Utilizes COTS and GOTS. Argus has never been an IT research program.
- Began experimental testing in December 2004 with support for Tsunami relief efforts.
- Coverage concentrated in Pacific Rim.
- In August 2005, a plan was requested to move Argus into global operation to track Avian Influenza.

History *(continued)*

- During 2005 and 2006, development work continued on IT platforms, software, and analytical taxonomies.
- Funded in mid-June 2006 to field an operational system.
- Began operations in late July, 2006.
- Within one month, achieved global reach with coverage of 195 of 196 US-recognized countries.
- Achieved initial operating capability in late November, 2006.
- Full operational capability was attained in July, 2007, and the final major system was delivered in January 2008.

Approach

- Assemble social disruption key word queries from SME-derived Indicators and Warnings (I&Ws).
- Acquire collection and modeling capabilities to capture and analyze articles from the World Wide Web.
- Develop and implement an automated cueing and alerting capability.

What We Don't Do

- Ground truthing
- Pathogen diagnostics

Argus is a cueing and alerting capability that complements the long established public health and attribution investigation approaches used by other organizations.

Summary

- Argus is changing the expectations for bioevent detection.
- The system has been reduced to practice on a global scale. Actively tracking avian influenza and 130 other infectious diseases.
- Reports sent to over 300 accounts (many with multiple users) in approximately 200 organizations.
- The Argus process can have much broader application in even tracking of other issues.

Summary *(continued)*

- The private sector has been engaged.
- Exploring other real time data sources.
- Completed and transferred the Argus Global Information System (AGIS). AGIS is more robust and stable than its predecessor. Third generation platform (Apollo) was delivered in January, 2008.
- Continuing OFA funding of R&D component to complement and support Argus.
- Exploring real time cueing of U.S. based hospital infrastructure.

Ellen P. Carlin, D.V.M.

Assistant Research Professor

Areas of Expertise

- Zoonoses, with a focus on viral and parasitic pathogens
- Emerging infectious disease epidemiology and policy
- U.S. biodefense policy
- Global health security policy

Professional Memberships

- American Veterinary Medical Association
- License to practice

Dr. Ellen Carlin is Assistant Resea
Science and Security with a facul
Microbiology and Immunology. H
emerging infections and adequa
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people, animals, and the environ
infectious disease projects in Lib
studies the adequacy and impac
biothreat risks. At Georgetown, E
Disease Master of Science progr

Ellen previously served as Senio
Alliance, where she is now Resea
consulting services in writing, ed
including as founding staff, Co-Di
Commission on Biodefense. In 2
Food and Drug Administration Ce
and other aspects of antimicrobia
Professional Staff with the U.S. H
Homeland Security (Peter T. King
handled medical preparedness, biodefense, and science and technology policy.
That position began as an American Veterinary Medical Association/American
Association for the Advancement of Science fellowship.

Ellen previously served as Senior Health and Policy Specialist at EcoHealth Alliance, where she is now Research Fellow. She has for years provided consulting services in writing, editing, and provision of technical expertise, including as founding staff, Co-Director, and Senior Advisor to the Bipartisan Commission on Biodefense. In 2013, she completed a fellowship with the U.S. Food and Drug Administration Center for Veterinary Medicine on data analysis and other aspects of antimicrobial resistance. Prior to that, she was Senior Professional Staff with the U.S. House of Representatives Committee on Homeland Security (Peter T. King, NY), where for more than five years, she handled medical preparedness, biodefense, and science and technology policy. That position began as an American Veterinary Medical Association/American Association for the Advancement of Science fellowship.

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Ellen works with her alma mater as Courtesy Lecturer at the Cornell College of Veterinary Medicine, where she teaches a class on the role of the federal government in animal health. She has worked or volunteered since 2007 as a small animal clinical veterinarian and continues to participate in low income and vaccine clinics, serving her interests in animal health and welfare, public health, and parasitology. She received a Bachelor of Science in biology from the College of Mount Saint Vincent and a doctorate in veterinary medicine from the Cornell College of Veterinary Medicine.

https://www.georgetown.edu › news › bill-and-hillary-clinton-u-s-and-foreign-policymakers...

Bill and Hillary Clinton, U.S. and Foreign ... - Georgetown University

Sep 30, 2022 · Bill **Clinton** first met Albright when she was working on the Michael Dukasis presidential campaign. The **Clintons** Remember Albright. The day's final conversation between Bill and Hillary **Clinton** was moderated by Ambassador Melanne Verveer (I'66, G'69), executive director of the **Georgetown** Institute for Women, Peace and Security, who knew the former president during their time as students ...

http://biodefense.georgetown.edu/projects/argus.aspx Go APR MAY JUL
6 captures 20 2007 2008
20 May 2007 - 15 Dec 2012 2006 About this

Division of Integrated BioDefense

ISIS Center, Georgetown University Medical Center

Skip Navigation Links.
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- Argus
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Project Argus

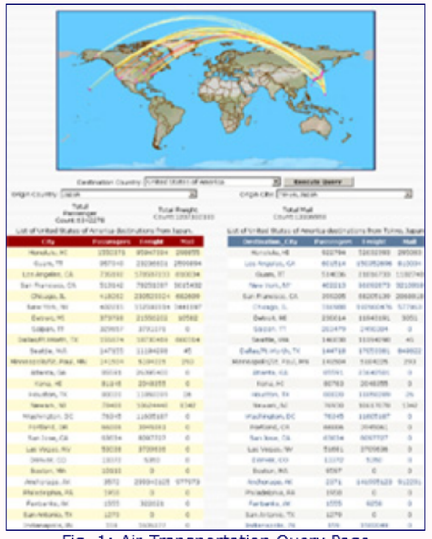


Fig. 1: Air-Transportation Query Page

The frequency of biological events with a potential impact on homeland security is increasing, and current disease surveillance systems in the United States (U.S.) have been inefficient in their capacity to detect these events in a timely fashion. The clear and present danger to the United States spans infectious diseases of humans, animals, and plants.

Indications and Warnings (I&Ws) alert U.S. responders of an imminent bioevent weeks to months in advance. I&Ws are markers occurring globally, outside of U.S. borders, before an outbreak can affect U.S. interests, forces, citizens, or territory, thus allowing the U.S. time to respond. In effect, I&Ws can prime the national response infrastructure by alerting agencies of an evolving threat that could ultimately be catastrophic. Retrospective analyses of major bioevents have demonstrated the presence of multiple I&Ws were present in multiple data sources weeks to months in advance, which were not recognized and utilized properly by the national response community.

For the U.S. to meet present and future biothreats that span agricultural, animal, and human considerations, an integrative strategy for information discovery, exploitation, and effective proactive use by the response community is critical. I&Ws provide a key component for integration within the U.S. biosurveillance portfolio, enabling earlier warning potential. Project Argus is the first attempt to integrate I&Ws in effort to detect catastrophic bioevents on an international scale. The Argus system serves as a primer for U.S. countermeasure response plans in the context of a potentially catastrophic bioevent. Project ARGUS is jointly funded by the US Army Medical Research and Materiel Command Telemedicine and Advanced Technology Research Center (USAMRMC-TATRC) and the Department of Homeland Security.

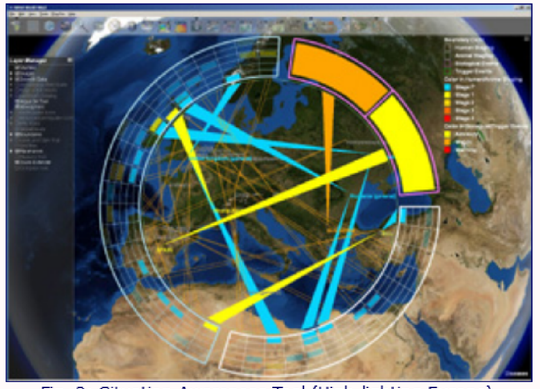


Fig. 2: Situation Awareness Tool (High-lighting Europe)

Contact Information
2115 Wisconsin Ave. NW, Suite 603 Washinton, DC 20007
Division Director: James M. Wilson, MD
e-mail: wilson@isis.georgetown.edu

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Imaging Science and Information Systems (ISIS) Center - Georgetown University

Joined in March 2007

Do you work for Imaging Science and Information Systems (ISIS) Center - Georgetown University? **Become an administrator**

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| http://www.isis.georgetown.edu

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About Us

The Imaging Science and Information Systems (ISIS) Center, under the Department of Radiology at the Georgetown University Medical Center, is a medical research organization with over 60 full-time faculty and staff specializing in the use…

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Disaster Economics
Disinformation
Domestic Terrorism in the US
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Energy Security
Extreme Heat
Federal Workforce Challenges
Fentanyl and Opioids
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Human Trafficking
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College Says It Owns Global Pandemic Warning System

NEWS DESK / August 3, 2009

WASHINGTON (CN) - Georgetown College sued two former employees who refuse to give up their patent rights to inventions for "Project Argus," a federally funded project for "technology capable of supporting a worldwide biosurveillance system" that can detect outbreaks of disease before they become pandemics.

Georgetown says six joint inventors from Georgetown worked on Project Argus inventions, but defendants Dr. James Wilson and Mark Polyak refused to assign their rights to the university when they resigned in spring 2008.

Georgetown's Imaging Science and Information Center collaborated with the nonprofit Mitre Corp. to create Argus, which was awarded the National Intelligence Medallion in 2008, the college said.

Georgetown says six joint inventors from Georgetown worked on Project Argus inventions, but defendants Dr. James Wilson and Mark Polyak refused to assign their rights to the university when they resigned in spring 2008.

Georgetown's Imaging Science and Information Center collaborated with the nonprofit Mitre Corp. to create Argus, which was awarded the National Intelligence Medallion in 2008, the college said.

Wilson spoke about the project at a 2005 Georgetown conference on infectious diseases, hailing Argus as the first attempt to produce intelligence on foreign bioevents so that the United States can avert a catastrophic epidemic.

Named after the 100-eyed sentinel from Greek mythology, Argus technologies study early indications and warnings of infectious disease to give responders notice before an epidemic peaks and is harder to contain.

At the 2005 Georgetown conference, another speaker introduced a doctrine of biosurveillance that would govern the project's access to "sensitive material" but not classified data in monitoring outbreaks.

"Because no single public law governs such heterogeneous data, investigators have analyzed numerous sources, including federal laws, Executive Orders

"Because no single public law governs such heterogeneous data, investigators have analyzed numerous sources, including federal laws, Executive Orders, international directives, agency policies and procedures, Congressional testimony, and reports by governmental and nongovernmental bodies [to create] the Biosurveillance Doctrine, a document that thoroughly explains conditions under which Project Argus will acquire, analyze, protect, and use data," Georgetown said in a statement about the conference.

After three years of development, Argus became operational in June 2007 and has already detected outbreaks before they became pandemics, according to a 2008 article in Security Management Magazine.

Argus followed the appearance of Ebola in the Democratic Republic of the Congo, the spread of the H5N1 avian flu from China into Russia and a minor hoof-and-mouth outbreak in the United Kingdom.

Security Risk Solutions, a South Carolina-based consulting firm, supports the project in a statement on its Web site.

"Instead of waiting for reports from local doctors and hospitals, Argus uses software that treats the Earth's communications almost like a giant EKG,

Argus followed the appearance of Ebola in the Democratic Republic of the Congo, the spread of the H5N1 avian flu from China into Russia and a minor hoof-and-mouth outbreak in the United Kingdom.

Security Risk Solutions, a South Carolina-based consulting firm, supports the project in a statement on its Web site.

"Instead of waiting for reports from local doctors and hospitals, Argus uses software that treats the Earth's communications almost like a giant EKG, looking for certain kinds of spikes in global information networks," Security Risk says. "Search programs zero in on key words on the Internet and in news media that might indicate an epidemic, such as heavy rates of absenteeism, runs on pharmaceutical drugs, and migration away from villages and towns."

Georgetown says its employment policy requires the defendants to surrender their patent rights and it seeks an order directing them to do so. Georgetown is represented by Thomas Hentoff with Williams & Connolly.

Categories: UNCATEGORIZED

Chapter 2

DESIGNING ETHICAL PRACTICE IN BIOSURVEILLANCE

The Project Argus Doctrine

JEFF COLLMANN[1,*] and ADAM ROBINSON[2]

CHAPTER OVERVIEW

Biosurveillance entails the collection and analysis of information needed to provide early warning of outbreaks of infectious disease, both naturally occurring and intentionally introduced. Data derived from repositories containing various types of sensitive information may be required for this purpose, including individually identifiable, copyrighted, and proprietary information. The Project Argus Biosurveillance Doctrine was developed to ensure that ethical and legal principles guide the collection and handling of such information. Project Argus does not, however, use individually identifiable information or any material derived from individually identifiable information for any phase of the project. Further, Project Argus is not used for purposes of law enforcement, counterterrorism, or public health surveillance. This chapter details why and how the doctrine was developed and summarizes its guiding principles and key elements.

Keywords: Biosurveillance; Sensitive information; Information protection; Privacy

[1*] *O'Neill Institute for National and Global Health Law, Disease Prevention and Health Outcomes, School of Nursing and Health Studies, Georgetown University Medical Center, Box 571107, 3700 Reservoir Rd, NW, Washington, DC 20057–1107, USA, collmanj @georgetown.edu*

[2] *The MITRE Corporation, 7515 Colshire Drive, McLean, VA 22102, USA*

D. Zeng et al. (eds.), *Infectious Disease Informatics and Biosurveillance*, Integrated Series in Information Systems 27, DOI 10.1007/978-1-4419-6892-0_2,

2. BACKGROUND

Project Argus developed the technical and doctrinal requirements for an integrated, multisource information system designed to perform global bio-

surveillance for epidemics; biological accidents; and bioattacks on humans, animals, and plants [1].

The ethical issues surrounding the development and maintenance of such a system have been a key consideration from the outset of Project Argus. No single public law or set of regulations governs the handling and protection of the broad range of sources, types, security classifications, and potential uses of the information to be collected and analyzed. Therefore, the Project Argus doctrine team was formed to develop the necessary guidance. The resulting biosurveillance doctrine sets forth explicit principles, management structures, policies, procedures, and technical design requirements intended to ensure the ethical handling and use of sensitive information by project participants. In this respect, a strong moral, organizational, and technical divide exists between Project Argus and initiatives that have drawn the censure of Congress, the media, and the American public for their failure to ensure such protections. After describing the methods used to develop the doctrine, we provide a high-level view of its guiding principles and key elements.

It should be noted that the version of the doctrine presented here applies only to the acquisition, archiving, analysis, and presentation of biosurveillance information in Project Argus. The doctrine team analyzed a broad set of sensitive information, including individually identifiable, copyrighted and public information. We include our analysis of and approach for handling this broad set of sensitive information for the sake of completeness and as a guide to others. Project Argus does not use any individually identifiable information in any phase of the project.

[House Hearing, 110 Congress]
[From the U.S. Government Printing Office]

ONE YEAR LATER--IMPLEMENTING THE BIOSURVEILLANCE REQUIREMENTS OF THE 9/11 ACT

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HEARING

before the

SUBCOMMITTEE ON EMERGING
THREATS, CYBERSECURITY,
AND SCIENCE AND TECHNOLOGY

of the

COMMITTEE ON HOMELAND SECURITY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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JULY 16, 2008

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Serial No. 110-128

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Printed for the use of the Committee on Homeland Security

<GRAPHIC OMMITTED> See the end of the file for all omitted graphics

ONE YEAR LATER, IMPLEMENTING THE BIOSURVEILLANCE REQUIREMENTS OF THE 9/11 ACT

Wednesday, July 16, 2008

U.S. House of Representatives,
Committee on Homeland Security,
Subcommittee on Emerging Threats, Cybersecurity, and
Science and Technology,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:19 p.m., in Room 311, Cannon House Office Building, Hon. James R. Langevin [Chairman of the subcommittee], presiding.

Present: Representatives Langevin, Christensen, Pascrell, and McCaul.

Mr. Langevin. The subcommittee will come to order.

The subcommittee is meeting today to receive testimony on the current state and future course of the National Biosurveillance Integration Center, NBIC, and Project BioWatch.

Before I begin my opening statement, I wanted to mention to the witnesses that there is a committee rule that testimony is supposed to be in 48 hours in advance. We got the DHS testimony this morning. We can't do business like that, and I will caution you about ever doing it again. I don't want to have the testimony received by this subcommittee that late ever again. It is unacceptable. We just can't do business that way.

With that, good afternoon. I would like to thank my colleagues for their participation, and I welcome our witnesses here today.

As this committee is well aware, the threat of biological attack is real and potentially catastrophic. As the Chairman of the subcommittee, I have made it a priority to address the most glaring vulnerabilities facing our Nation, and this is certainly one of them. Of equal or greater concern, of course, is the possibility that a naturally occurring disease outbreak could grow to epidemic proportions. We have held numerous hearings on how better to protect against biological attack, and today we are continuing those efforts.

Today, our focus will be on determining whether the biosurveillance requirements included in the Implementing Recommendations of the 9/11 Act of 2007, which became law on August 3, 2007, have been properly implemented. The 9/11 Act included two key sections regarding our Nation's biosurveillance capabilities. Section 1101 authorized the National Biosurveillance Integration Center, or NBIC, and



Biological Threat Detection and Response Challenges Remain for BioWatch (REDACTED)

UNITED STATES. DEPARTMENT OF HOMELAND SECURITY. OFFICE OF INSPECTOR GENERAL

From the Highlights: "The BioWatch Program (BioWatch) is intended to detect biological agents and provide early warning in the event of a biological attack. We conducted this audit to determine to what extent BioWatch's information sharing ensures nationwide readiness in response to biological terrorism threats."

Details

URL	https://www.hsdl.org/c/view?docid=850663
Publisher	United States. Department of Homeland Security. Office of Inspector General
Report Number	Department of Homeland Security, Office of Inspector General, Report No. OIG-21-22
Date	2 Mar, 2021
Copyright	Public Domain
Retrieved From	Department of Homeland Security Office of Inspector General: www.oig.dhs.gov/

How much money went into the Deparment of Homeland Security's BioWatch program?

↘ PERPLEXITY

According to the search results, the funding for the BioWatch program, which is part of the Department of Homeland Security, has varied over the years. Here is a breakdown of the funding information found:

- FY2003: The DHS reportedly spent approximately $40 million on the BioWatch program [1].
- 2007: The original 31 city program cost $60 million [2].
- FY2013-FY2014: Proposed funding for programs in the DHS Office of Health Affairs was reduced to $101.3 million, a 24% reduction from estimated FY2013 funding levels [3].
- FY2022: The DHS budget provides $52.2B in net discretionary funding, with an additional $18.8B for the Disaster Relief Fund [4].
- Current funding: There is no information in the search results about the current funding for the BioWatch program.

Therefore, it is unclear how much money went into the Department of Homeland Security's BioWatch program overall, as the funding has varied over the years and there is no information about the current funding.

1 fas 2 wikipedia 3 nih 4 dhs

What is the ISIS center at Georgetown University?

PERPLEXITY

The ISIS Center at Georgetown University is not related to the terrorist organization ISIS. Instead, it stands for Imaging Science and Information Systems Center. It is a research center under the Department of Radiology at the Georgetown University Medical Center [1]. The center focuses on the development of advanced medical imaging technologies and information systems [2]. It was established in the 1980s and 1990s and was led by Seong K. Mun [3]. The center is not to be confused with the Center for Security Studies, which is another academic research center in the School of Foreign Service that offers a master's degree program [4].

1 idealist 2 georgetown 3 georgetown 4 georgetown

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what is the focus of the ISIS center at Georgetown University

PERPLEXITY

The ISIS Center at Georgetown University is the Imaging Science and Information Systems Center, which is a research center under the Department of Radiology at the Georgetown University Medical Center [1]. The center focuses on the development of advanced medical imaging technologies and information systems [1]. The center was established in the 1980s and 1990s and was led by Seong K. Mun [2]. The center is not related to the terrorist organization ISIS [1].

1 georgetown 2 idealist

What connection is there between Georgetown University's ISIS Center and project argus?

PERPLEXITY

There is no clear connection between Georgetown University's ISIS Center and Project Argus. However, there is a mention of Georgetown University's Argus Project in a 2007 report on global health challenges [1]. It is unclear what this project refers to, but it is not related to the ISIS Center. The ISIS Center is a research center under the Department of Radiology at the Georgetown University Medical Center that focuses on the development of advanced medical imaging technologies and information systems [2]. It was established in the 1980s and 1990s and was led by Seong K. Mun [3]. Project Argus, on the other hand, is a global detection and tracking system for the early detection of biological events [4]. It was started on Earth Day, April 21, 1996, with just five operational radio telescopes [4].

1 govinfo 2 idealist 3 georgetown 4 courthousenews

What is the outcome of the lawsuit between Georgetown College and the former employees over Project Argus patent rights

PERPLEXITY

Georgetown College sued two former employees who refused to give up their patent rights to inventions for "Project Argus," a federally funded global pandemic warning system [1]. The outcome of the lawsuit is unclear, as there are no recent reports on the case. However, the lawsuit suggests that Georgetown College claims ownership of the patent rights to Project Argus [1]. It is possible that the case was settled out of court or is still ongoing. There are no further details on the outcome of the lawsuit.

Who are the key researchers involved in Project Argus at Georgetown University

PERPLEXITY

Jeffrey Collmann is one of the key researchers involved in Project Argus at Georgetown University [1]. Collmann helped found Project Argus, an award-winning biosurveillance program [1]. However, it is unclear who else was involved in the project, as there are no further details on the researchers involved. The project began on Earth Day, April 21, 1996, with just five operational radio telescopes [1]. The scope of the project had expanded by November 2000 [1]. It is unclear if the project is still active at Georgetown University, as there are no recent reports on the project. However, there is a company called Project Argus that provides supply chain solutions [2] [3].

What is the significance of Project Argus in the field of biosurveillance?

PERPLEXITY

Project Argus is a biosurveillance program that was established as a prototype research effort to explore the use of indicators to detect and track biological events, crises, and disasters [1]. The program was founded by Jeffrey Collmann, who currently works with the Office of the Senior Vice President of Research at Georgetown University [2] [3]. The program is significant in the field of biosurveillance because it is a global detection and tracking system for the early detection of biological events [4]. The Project Argus Biosurveillance Doctrine was developed to ensure that ethical and legal principles guide the collection and handling of information [5]. An integrated biosurveillance program is vital to help protect the homeland from bioterrorism, unintentional introductions (e.g., Foot-and-Mouth Disease), and naturally occurring biological events, such as pandemic influenza [1]. Biosurveillance refers to monitoring for potential signs of biological events with the intent of early detection of that event to permit the timely response to mitigate consequences [1]. Should an event occur, biosurveillance and detection allow the monitoring of an outbreak as it happens and provide accurate situational awareness to first responders [1].

1 fas 2 georgetown 3 georgetown 4 nih 5 academia

Who is Ellen P Carlin and what is her connection to Georgetown University and EcoHealth Alliance?

PERPLEXITY

Ellen P. Carlin is a veterinarian and Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University [1][2][3][4]. She has a primary faculty appointment within the Department of Microbiology and Immunology at Georgetown University [2]. Her research interests are in zoonotic disease, global health security, and One Health approaches to disease prevention and control [5]. Carlin is also a Research Fellow and Senior Health and Policy Specialist at EcoHealth Alliance, a non-profit organization that focuses on the intersection of human, animal, and environmental health [1][5][6]. At EcoHealth Alliance, Carlin works on projects related to zoonotic disease surveillance, risk assessment, and policy development [5][6]. She received a bachelor's of science in biology from the College of Mount Saint Vincent and a doctorate in veterinary medicine from Cornell University [6].

1 georgetown 2 georgetown 3 twitter 4 linkedin 5 researchgate 6 ecohealthalliance

Has Ellen Carlin collaborated with any other institutions or organizations on her research

PERPLEXITY

Yes, Ellen Carlin has collaborated with other institutions and organizations on her research. Here are some examples:

- Smithsonian Conservation Biology Institute: Carlin is a research associate with the Smithsonian Conservation Biology Institute, where she works with the Global Health Program to develop research and capacity [1].
- Parapet Science & Policy: Carlin is a consultant with Parapet Science & Policy, a consulting firm that provides scientific and policy expertise to government agencies, non-profit organizations, and private companies [2].
- EcoHealth Alliance: Carlin is a Research Fellow and Senior Health and Policy Specialist at EcoHealth Alliance, where she works on projects related to zoonotic disease surveillance, risk assessment, and policy development [1][3][4].
- Georgetown University: Carlin is an Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University, with a primary faculty appointment within the Department of Microbiology and Immunology [5][6]. At Georgetown, Carlin conducts research on zoonotic disease, global health security, and One Health approaches to disease prevention and control [3].

Overall, Carlin has collaborated with a variety of institutions and organizations on her research, including the Smithsonian Conservation Biology Institute, Parapet Science & Policy, EcoHealth Alliance, and Georgetown University.

1 ecohealthalliance 2 linkedin 3 twitter 4 acrl 5 researchgate

How is Ellen Carlin connected to William Karesh?

PERPLEXITY

Ellen Carlin is connected to William Karesh through their work at EcoHealth Alliance. William Karesh is the Executive Vice President for Health and Policy at EcoHealth Alliance [1], while Ellen Carlin is a Research Fellow and Senior Health and Policy Specialist at the same organization [2]. Both Karesh and Carlin work on projects related to zoonotic disease surveillance, risk assessment, and policy development [1] [2].

1 researchgate 2 ecohealthalliance

What is the connection between William Karesh and Georgetown University

PERPLEXITY

There is no information in the provided search results about a direct connection between William Karesh and Georgetown University. However, both Karesh and Ellen Carlin work on zoonotic disease research and policy development, and Carlin is an Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University [1] [2]. It is possible that Karesh has collaborated with Georgetown University researchers on zoonotic disease research, but there is no information in the provided search results to confirm this.

1 georgetown 2 researchgate

What is William Karesh's connection to "One Health"

PERPLEXITY

William Karesh is a champion of the "One Health" approach, which is an integrated approach to animal, human, and environmental health [1][2][3]. He is an internationally recognized authority on One Health and has been involved in One Health initiatives in various countries, including Brazil, Chile, and Colombia [1][4]. Karesh is the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics [5]. He has also co-authored articles on the importance of One Health and related concepts, such as Planetary Health and EcoHealth, in addressing complex health threats [6].

1 nih 2 foreignaffairs 3 genevaenvironmentnetwork 4 frontiersin

What are some notable achievements or initiatives related to One Health that William Karesh has been involved in

↘ PERPLEXITY

William Karesh has been involved in several notable achievements and initiatives related to One Health, including:

- Coining the term "One Health": In 2003, Karesh coined the term "One Health" to describe the interdependence of healthy ecosystems, animals, and people [1]. This term has since become widely used in the field of public health and has helped to promote a more integrated approach to health.
- USAID Emerging Pandemic Threats PREDICT-2 program: Karesh is the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics [2]. This program has been instrumental in identifying and responding to emerging infectious diseases, including COVID-19.
- Wildlife Disease Association: In 2019, Karesh was awarded the Wildlife Disease Association's highest honor for his contributions to the field of One Health implementation [3]. This award recognized Karesh's leadership in promoting a more integrated approach to health and his work on zoonotic disease surveillance and control.

- Co-authoring articles on One Health: Karesh has co-authored articles on the importance of One Health and related concepts, such as Planetary Health and EcoHealth, in addressing complex health threats [4]. These articles have helped to raise awareness of the need for a more integrated approach to health and have provided guidance on how to achieve this goal.
- EcoHealth Alliance: Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance, where he works on projects related to zoonotic disease surveillance, risk assessment, and policy development [5]. EcoHealth Alliance is a non-profit organization that focuses on the intersection of human, animal, and environmental health, and Karesh's work at the organization has helped to promote a more integrated approach to health.

1 biodefensecommission 2 ecohealthalliance 3 ecohealthalliance

4 foreignaffairs 5 aspeninstitute

What connections are there between "One Health" and the Bill and Melinda Gates Foundation?

↘ PERPLEXITY

There are several connections between "One Health" and the Bill and Melinda Gates Foundation, as evidenced by the provided search results:

- Funding: The Bill and Melinda Gates Foundation has provided funding for One Health initiatives, such as the One Health Neglected Zoonotic Disease and Fellowship Fund Support [1].
- Grants: The Gates Foundation has also provided grants to organizations like the Consortium of Universities for Global Health to support One Health initiatives [2].
- Interest: The Gates Foundation has expressed interest in the One Health approach and its potential to improve global health [3] [4].
- Meetings: The Ohio State Global One Health Initiative team has met with the Bill and Melinda Gates Foundation core team members to discuss One Health research approaches [5].

Overall, the Bill and Melinda Gates Foundation has shown interest in and provided support for One Health initiatives, recognizing the interconnectedness of human, animal, and environmental health.

1 gatesfoundation 2 cugh 3 onehealthinitiative 4 ucalgary 5 osu



William Karesh

EXECUTIVE VICE PRESIDENT; ECOHEALTH ALLIANCE, SOCRATES PROGRAM

Dr. William (Billy) Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance.

Dr. William (Billy) Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance. He serves as the inter-project liaison for the USAID Emerging Pandemic Threats PREDICT-2 program (a $140 Million effort to prevent infectious diseases in 30 countries) and is a member of World Health Organization's IHR Roster of Experts. Dr. Karesh also serves as the President of the World Organization for Animal Health (OIE) Working Group on Wildlife. In 2016, he was appointed as a member of the Council on Foreign Relations.

Dr. Karesh has pioneered initiatives focusing attention and resources on solving problems created by the interactions among wildlife, people, and their animals. In 2003, he coined the term "One Health" to describe the interdependence of healthy ecosystems, animals and people and the term has been adopted by many organizations, including the United Nations and the World Bank, in local and global health efforts. Dr. Karesh has created dozens of initiatives to encourage linkages among public health, agriculture and environmental health agencies and organizations around the world. He has personally lead programs and projects in over 45 countries, covering terrain from Argentina to Zambia.

In addition to his work in the private non-profit sector, Dr. Karesh has also worked for the USDA, DOD and DOI. He served as a consultant for the Food and Agriculture Organization of the U.N., and is currently on the Steering Committee of OFFLU (OIE-FAO Network of Expertise for Animal Influenzas). Dr. Karesh is internationally recognized as an authority on the subject of animal and human health linkages and wildlife. He has published over one hundred and eighty scientific papers and numerous book chapters, and written for broader audience publications such as *Foreign Affairs.*



News

Important One Health Message from the Bill & Melinda Gates Foundation

September 11, 2013

Important One Health Message from the Bill & Melinda Gates Foundation

"Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. Our Grand Challenges Explorations program fosters early-stage discovery research to expand the pipeline of ideas for solving our greatest global health and development challenges. Launched in 2008 with a $100 million commitment from the foundation, Grand Challenges Explorations grants have already been awarded to more than 850 researchers from more than 50 countries. Until November 12, 2013, we are accepting applications on five topics, including "One Health" Concept: Bringing Together Human and Animal Health for New Solutions.



Gates Foundation Initiative

Overview

In 2018 CUGH secured a grant from the Bill and Melinda Gates Foundation (BMGF) to work with the US academic community to increase support for US leadership and funding for global health. To achieve this objective, CUGH collaborated with its members, and CEPH-accredited institutions, to inform Congresspersons and State legislators as well as the general public on the value of global health to their state and the nation. As part of this project, CUGH connected elected officials with

Our Work

Past Projects

Sustaining Technical and Analytic Resources (STAR) Project

Gates Foundation



Collaboration: The Ohio State Global One Health Initiative team has met with the Bill and Melinda Gates Foundation core team members to discuss One Health research approaches [3]. The Gates Foundation also collaborates with partners in over 130 countries to address global health issues, including One Health [4] [5].

What connection to the PREDICT program is there with the CIA?

↘ PERPLEXITY

There is a connection between the PREDICT program and the CIA, as the program has been accused of having ties to the CIA. The PREDICT program is part of the USAID's Emerging Pandemic Threats program and is led by the UC Davis One Health Institute [1]. The program seeks to identify new emerging infectious diseases that could become a threat to human health by focusing on wildlife that are most likely to carry zoonotic diseases [2]. However, in 2020, the program was shut down by the Trump administration, and it was reported that the program had been accused of having ties to the CIA. The accusations were based on the fact that the PREDICT program had worked with the Defense Threat Reduction Agency, which is part of the Department of Defense and has been known to work with the CIA. However, the PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health.

1 predict 2 ecohealthalliance

Is there any evidence of CIA involvement in the PREDICT program

PERPLEXITY

There is no conclusive evidence of CIA involvement in the PREDICT program. However, there have been accusations of ties between the PREDICT program and the CIA. The accusations were based on the fact that the PREDICT program had worked with the Defense Threat Reduction Agency, which is part of the Department of Defense and has been known to work with the CIA [1]. The PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health [2]. While the CIA has been involved in disease intelligence and analysis dedicated to uncovering epidemics, such as Project IMPACT in the mid-1960s [3], there is no evidence that the CIA has been directly involved in the PREDICT program.

1 cia 2 go 3 predict

What is the Project IMPACT and how is it related to disease intelligence

PERPLEXITY

Project IMPACT was a CIA program that was among the first in "disease intelligence," a field of espionage and analysis dedicated to uncovering epidemics [1]. The project aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities [2]. The program sought to "computerize disease information and derive trends, cycles, and predictions" to monitor the flu's progression [1]. As the disease spread south from China, and as the U.S. was in the middle of the Vietnam War, the CIA also used Project IMPACT to study the effects on the North Vietnamese army and the Viet Cong [1]. The CIA used the data to send "a warning" to "indigenous intelligence teams operating in Laos and Cambodia to take special precautions during these peak influenza periods" [1].

The PREDICT program, on the other hand, is a USAID initiative that seeks to aggressively pre-empt or combat diseases that could spark future pandemics [3] [4]. The program aims to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens [5]. The PREDICT program has been successful in identifying new emerging infectious diseases that could become a threat to human health [6]. While there is no evidence that the CIA has been directly involved in the PREDICT program, the CIA has been involved in disease intelligence and analysis dedicated to uncovering epidemics, such as Project IMPACT in the mid-1960s [1].

1 go 2 cia 3 usaid 4 usaid 5 usaid 6 usaid

services and disease reporting in rural areas was a logical outgrowth of this massive epidemic. Whether the ensuing decline of the disease was due to the extensive use of sulfadiazine or to the normal decline of the epidemic cycle was never ascertained. It was followed by other predicted disease outbreaks (i.e., hepatitis, measles), and a recurrence of a much less severe meningitis epidemic in the winter of 1967–1968. As a postscript, China's failure to prevent and control the spread of diseases was viewed by the USSR as a fundamental weakness of the Chinese health services and the Soviet Ministry of Health abruptly rescinded the 1960 Sino-Soviet agreement on mutual abolition of vaccination requirements for travellers between these countries.

Project IMPACT went global in the summer of 1968 when a new strain of influenza rolled out of China and within a short period of time affected one out of every four persons in the world. The strain was not an unusually lethal one but it was only by chance that it was not. Again, various Agency sources provided the first indication of the beginning of this worldwide pandemic when the disease moved from China via travellers to Hong Kong in late June. An estimated 500,000 cases resulted in Hong Kong alone including 30 percent of the personnel at the American Embassy. At this time a unique opportunity was available to review statistical data on influenza (a program to computerize disease information to derive trends, cycles and predictions had already been initiated under a CIA Project called BLACKFLAG); the current epidemic in Hong Kong was causing the highest incidence since the first Asian Type A2 epidemic of 1957. While the epidemic appeared to be progressing in a new way, initial

What was the CIA's Project BLACKFLAG?

PERPLEXITY

Project BLACKFLAG was a CIA program that tracked the spread of disease in the Soviet Union and North Vietnam and issued regular analyses of the political situation [1] [2]. It was part of the CIA's "disease intelligence" program, which was among the first in the field of espionage and analysis dedicated to uncovering epidemics [1] [2]. However, there is no further information in the provided search results about the specific objectives or activities of Project BLACKFLAG.

It is important to note that the term "black operation" or "black op" is used to describe covert or clandestine operations by government agencies, military units, or paramilitary organizations [3]. The term "black" may also be used as a generic term for any government activity that is hidden or secret [3]. For example, in the United States, some activities by military and intelligence agencies are funded by a classified "black budget," of which the details, and sometimes even the total, are hidden from the public and from most congressional oversight [3]. However, this is not directly related to the CIA's Project BLACKFLAG.

There are also other projects and programs named Project BLACKFLAG that are unrelated t

How did Project BLACKFLAG track the spread of the disease in the Soviet Union and North Vietnam

PERPLEXITY

Project BLACKFLAG tracked the spread of disease in the Soviet Union and North Vietnam and issued regular analyses of the political situation [1] [2]. The program sought to "computerize disease information and derive trends, cycles and predictions" to monitor the flu's progression [2]. The CIA was also able to warn its teams of operatives abroad through BLACKFLAG [3]. However, there is no information in the provided search results about how Project BLACKFLAG tracked the spread of disease in the Soviet Union and North Vietnam.

It is important to note that the CIA's Project IMPACT, which was merged with BLACKFLAG, aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities [4]. The program sought to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens [5]. The program has been successful in identifying new emerging infectious diseases that could become a threat to human health [5].

1 intelnews 2 go 3 google 4 cia 5 reuters

How did Project BLACKFLAG use computerized disease information to derive trends and predictions

↘ PERPLEXITY

According to the provided search results, Project BLACKFLAG used computerized disease information to derive trends and predictions. The program aimed to "computerize disease information and derive trends, cycles and predictions" to monitor the flu's progression [1]. However, there is no further information in the provided search results about how Project BLACKFLAG specifically used computerized disease information to derive trends and predictions.

It is important to note that the CIA's Project IMPACT, which was merged with BLACKFLAG, aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities [1][2]. The program sought to "computerize disease information and derive trends, cycles, and predictions" to monitor the flu's progression [1]. The program also sought to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens [3]. The program has been successful in identifying new emerging infectious diseases that could become a threat to human health [3].

1 go 2 cia 3 cdc

Project Impact: 'Disease intelligence' and how the CIA traced epidemics out of Cold War Asia

When a new flu strain emerged in Hong Kong, a CIA program "went global."

By **Lee Ferran**
June 20, 2020, 4:00 AM



Darrell M. Blocker, a former senior CIA officer who was head of the agency's Africa Division during the Ebola crisis in 2014, said the CIA's mission in disease intelligence is similar today as it was more than a half-century ago and is twofold: Uncovering what's really happening on the ground in countries during epidemics that don't like to share that information and attempting to predict what effect it could have on U.S. interests in the region.

"There's a side to the [disease] research they don't want people to know about. That's where the intelligence comes in," said Blocker, now an ABC News contributor. A spokesperson for the CIA declined to comment for this report.

Blocker said now the U.S. intelligence community can call on its vast, 17-organization-strong apparatus to assess what a disease is doing and how local governments are reacting. But in the mid-1960s, a young CIA was only then starting to appreciate the value of disease intelligence. According to the 1972 declassified CIA article titled "Intelligence Implications of Disease," it began with Project IMPACT.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

Disease intelligence 'going global'

While IMPACT was able to trace emergence of the meningitis outbreak in the closed communist country, in part by simply observing the movements of the Red Guard from one province to the next, it wasn't until the next outbreak, only months away, that the program expanded and "went global."

That's when a new strain of influenza appeared in Hong Kong and eventually snaked its way around the world. The virus "affected" one in four people on the planet, according to the CIA report. The 1968 flu pandemic is believed to have killed as many as 1 million people worldwide, including 100,000 in the U.S., as per the Centers for Disease Control and Prevention

Disease intelligence 'going global'

While IMPACT was able to trace emergence of the meningitis outbreak in the closed communist country, in part by simply observing the movements of the Red Guard from one province to the next, it wasn't until the next outbreak, only months away, that the program expanded and "went global."

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To monitor the flu's progression, Project IMPACT folded in an ongoing CIA effort known as BLACKFLAG, which sought to "computerize disease information and derive trends, cycles and predictions."

Within weeks, scientists were able to determine it was, indeed, a new strain of influenza, which they named Hong Kong/A2/68. (While the CIA study, citing "various [Central Intelligence] Agency sources," states flatly that the virus "moved from China via travelers to Hong Kong," a World Health Organization report from 1969 on the virus' origins says it is "not certain" it came from mainland China.)

As experts gathered information on the new virus, the World Health Influenza Center in London made a dire prediction.

"The emergence of a new strain [of influenza] occurs every 10-15 years and together with rapid transportation, and in the absence of specific vaccines, leads us to believe that the disease may cause extensive outbreaks throughout the world in the coming months," the center said, according to the CIA study.

transportation, and in the absence of specific vaccines, leads us to believe that the disease may cause extensive outbreaks throughout the world in the coming months," the center said, according to the CIA study.

Stumbles in the Soviet Union, warnings in Vietnam

Though the center's warning discussed the "rapid transportation" of people, at the time it was still predicted that it would take some seven months for the new flu to hit the then-Soviet Union, America's arch-nemesis in the Cold War and the focus of so much CIA attention already.

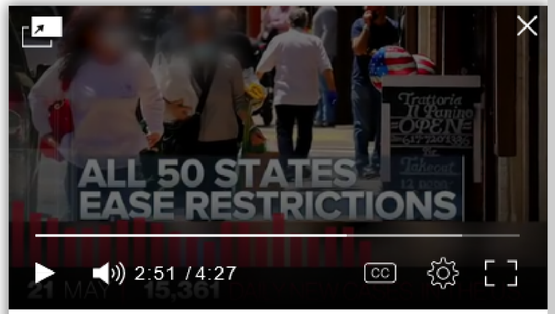
Still, the Soviets weren't able to prepare, the CIA article said.

"[T]he Soviets continued to vaccinate the urban population (about 75 percent) with the standard A2 vaccine which was shown even in August, to have very little protective value against [the] Hong Kong flu (this decision later was reported to be based on their inability to make the new vaccine in less than a year and their gamble that A2 vaccine would help)," the report said. "By late January, the flu was present in many Soviet cities and incidence rates began to increase sharply."

The Soviets hid information about the disease and purportedly interfered with the efforts of health care workers on the ground, according to the study.

In an early echo of the Trump administration's attempts to brand the current novel coronavirus the "Wuhan virus," the Soviets reportedly referred to the disease as "Mao's flu," in a reference to the then-leader of the Chinese Communist Party, Mao Zedong.





Reopened for business: Here's how states responded to coronavirus in May



A lab assistant inoculates fertile eggs with Hong Kong influenza virus at a drug company in West Point, Pa., Nov. 20, 1968. This is one step in the production of the much needed flu vaccine.

Getty Image, FILE

As the disease spread south from China, and as the U.S. was in the middle of the Vietnam War, the CIA also used Project IMPACT to study the effects on the North Vietnamese army and the Viet Cong.

"Staff personnel of the Special Assistant/Vietnam Affairs (SA/VA) were consulted, and together with their data on traffic routes, troop concentration, and locations of waystations (Binh Trams), made it possible to construct a model of the direction of the influenza epidemic," the CIA article said.

With that data and by monitoring reports of sickness and military requests for medicine, the CIA determined that "incapacitation rates ranged from about 40 to 70 percent and there was very good evidence that except for the isolation and quarantine of patients, no capability existed to specifically protect their military personnel by mass vaccinations."

Using the data, the CIA also sent "a warning" to "indigenous intelligence teams operating in Laos and Cambodia to take special precautions during these peak influenza periods."

In the end, the CIA report suggested that Project IMPACT was most successful in simply showing the value of the aggregation of data to help predict the impact of outbreaks.

"Disease intelligence can provide an initiating and vital role in the more familiar political, military and economic categories of intelligence," it says.

What are some current One Health research projects or initiatives that William Karesh is leading or involved in

PERPLEXITY

There is no information in the provided search results about specific One Health research projects or initiatives that William Karesh is currently leading or involved in. However, Karesh is the Executive Vice President for Health and Policy at EcoHealth Alliance, where he works on projects related to zoonotic disease surveillance, risk assessment, and policy development [1][2][3]. He is also the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics [2]. Karesh has been involved in One Health initiatives in various countries, including Brazil, Chile, and Colombia [4][5]. His work has helped to promote a more integrated approach to health on a global scale.

1 nih 2 ecohealthalliance 3 aspeninstitute 4 biodefensecommission

5 ecohealthalliance

Opportunities for Enhanced

DEFENSE, MILITARY, AND SECURITY SECTOR ENGAGEMENT IN GLOBAL HEALTH SECURITY

EcoHealth Alliance

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In addition to literature research, the following events and experts formed the backbone of this project's information gathering phases, and allowed for substantial deliberation of results and conclusions:

TABLE OF CONTENTS

Abbreviations 2
A note on definitions. 3
Executive Summary. 4
Introduction 12
Security, defense, and COVID-19 14
Securitization of public health. 15
Purpose of this evaluation 19
Chapter 1: Historical Context and the Intentional Threat . . . 20
The relevance of the intentional biological threat 21
Chapter 2: The Roles of the Sectors. 24
Defense 27
Military. 28
Security 33
Chapter 3: Domestic Engagement as Foundational 36
Challenges with DMS engagement in domestic health security 37
The role of the United States domestically and globally 39
Chapter 4: Global Engagement and Multilateralism 52
Multilateral efforts 53
Who's driving global health security? 54
Making the global health security table multisectoral 56
Chapter 5: The Choices Ahead 60
Benefits of engagement 61
Appropriate limitations to engagement. 64
Chapter 6: Conclusions and Roadmap 66
Appendix A: Process and Acknowledgements 75
References 77

FIGURES, TABLES, AND BOXES

Figures

Figure 1: U.S. funding for global health security FY2009-2020

Figure 2: Roadmap for optimized engagement of Defense, Military, and Security in global health security

Boxes

Box 1: Two Militaries, Two Ebolas

Box 2: Canada's Weapons Threat Reduction Program

Box 3: The World Health Organization's Military-Civilian Collaboration Initiative for Health Security

Tables

Table 1: Pillars and supporting functions for global health security

Table 2: Annual public threat assessments from the U.S. Office of the Director of National Intelligence that assess infectious disease as a national security threat

Table 3: The codified role of the U.S. Department of Defense in health security and global health security

Table 4: Dedicated U.S. global health security spending – key departments and agencies

Opportunities for Enhanced

DEFENSE, MILITARY, AND SECURITY SECTOR ENGAGEMENT IN GLOBAL HEALTH SECURITY

EcoHealth Alliance

Metrics

- 1.6 billion doses procured
- 582 million doses delivered domestically; 150 million internationally
- Distribution to more than 91,000 sites
- 86 percent of 18+ population received one shot; 207 million Americans fully vaccinated
- 87 percent of ≥65 population, the most vulnerable demographic, fully vaccinated
- 75 million booster doses administered
- 7 million pediatric (ages 5–11) doses administered between 1 November and December 2021
- Managed allocation and ordering of 3.9 million courses of monoclonal antibodies[10]

At the time that the CAG was dissolved, the entire U.S. resident population had available and equitable access to a COVID-19 vaccine. The COVID-19 domestic countermeasures production ecosystem was more robust and secure; vaccine waste had been minimized; an IT architecture that provided data on allocations, distribution, and administration was in place; and booster, adolescent, and pediatric vaccine campaigns were ongoing.

Most importantly, the vaccines and therapeutics produced and delivered by the CAG averted an estimated 1.1 million additional COVID-19 deaths and more than 10.3 million additional COVID-19 hospitalizations in the United States as of November 2021.[11] This achievement supported and nested with the recovery outlined in the *National Strategy for COVID-19 Response and Pandemic Preparedness* (January 2021).[12] The CAG's efforts arguably saved more American lives than any other DOD effort in U.S. history.

Operation Warp Speed (OWS, since renamed the Countermeasures Acceleration Group -- CAG)

OWS/CAG Timeline

13 March 2020 Declaration of national emergency concerning COVID-19

15 May 2020 Formation of Operation Warp Speed

5 June 2020 MOU signed by the secretary of HHS and secretary of defense to expedite vaccines to 300 million Americans

July 2020 Large-scale efficacy trials begin

11 December 2020* First vaccine receives emergency use authorization (EUA)

24 February 2021 National emergency declaration extended for one year

1 May 2021 OWS was renamed the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG); new MOU takes effect

10 May 2021* First vaccine receives EUA for adolescents (ages 12–15)

September 2021* CAG assigned mission of managing distribution of therapeutics

1 November 2021* EUA issued for pediatrics (ages 5–11)

19 November 2021* Booster dose authorized for all vaccinated individuals 18 and older

31 December 2021 CAG dissolved, and mission transitioned to the HHS Coordination Operations and Response Element (HCORE)

*The issuance of each EUA and the assumption of the therapeutics mission involved planning and executing the production, delivery, and administration of tens of millions of doses to tens of thousands of individual locations.

HHS Sec June 2020 signs MOU to expedite vaccines to 300 Million Americans

July 2020-efficacy trials

Feb. 2021: 1st vaccine get EUA

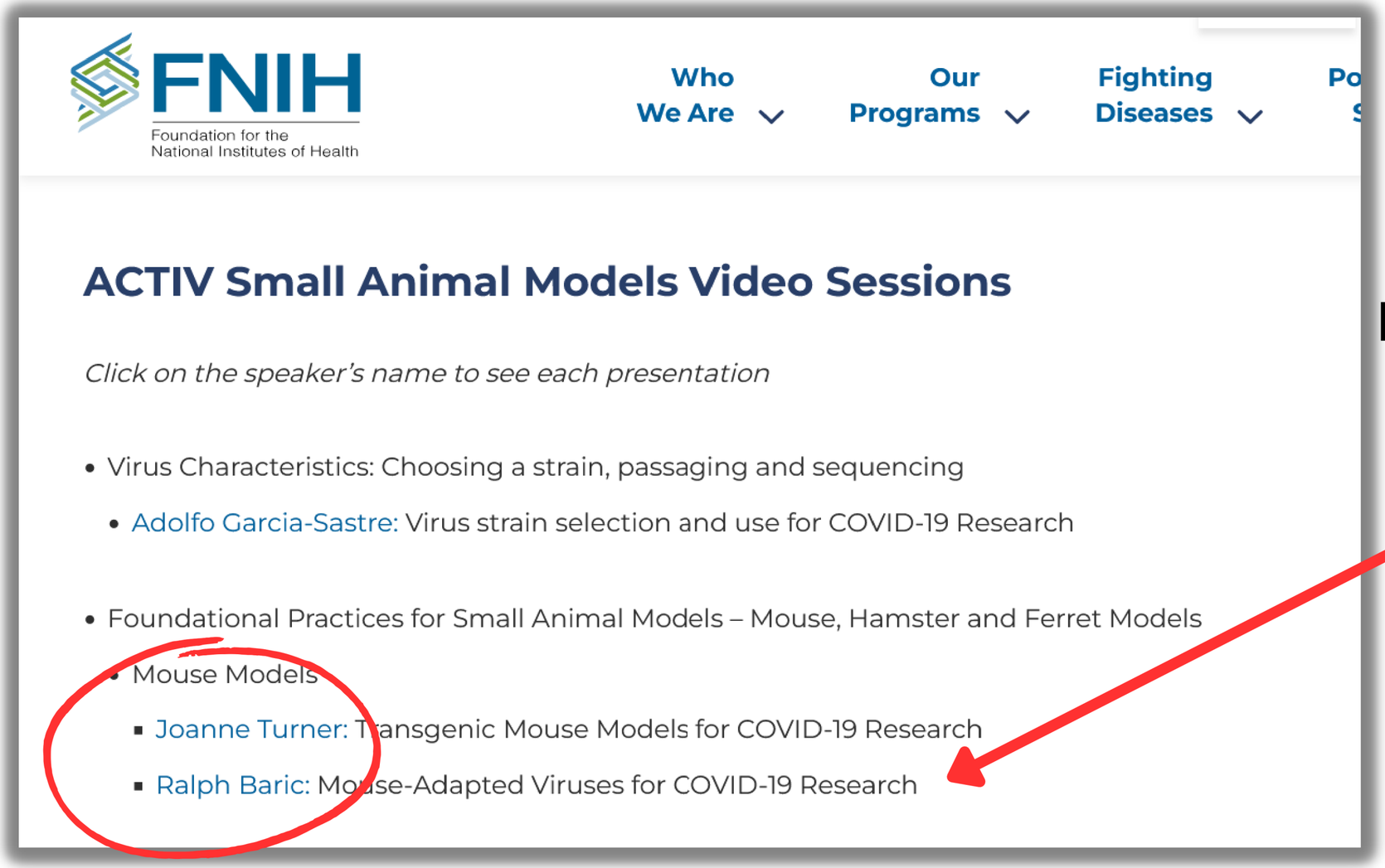
May. 2021: 1st vaccine get EUA for 12-15

Nov. 2021: 1st vaccine get EUA for 5-11

Dec. 2021: OWS-CAG- HCORE

https://www.usmcu.edu/Outreach/Marine-Corps-University-Press/MCU-Journal/JAMS-vol-13-no-1/Operation-Warp-Speed/

ACTIV Accelerating COVID-19 Therapeutic Interventions and Vaccines (est 2020)
FNIH: FOUNDATION FOR THE NATIONAL INSTITUTE OF HEALTH



FNIH
Foundation for the National Institutes of Health

Who We Are | Our Programs | Fighting Diseases | Po

ACTIV Small Animal Models Video Sessions

Click on the speaker's name to see each presentation

- Virus Characteristics: Choosing a strain, passaging and sequencing
  - Adolfo Garcia-Sastre: Virus strain selection and use for COVID-19 Research
- Foundational Practices for Small Animal Models – Mouse, Hamster and Ferret Models
  - Mouse Models
    - Joanne Turner: Transgenic Mouse Models for COVID-19 Research
    - Ralph Baric: Mouse-Adapted Viruses for COVID-19 Research

FOUNDATION FOR THE NATIONAL INSTITUTE OF HEALTH's Animal Model Presenters 2021, for Mouse Models is

RALPH BARIC

https://fnih.org/sites/default/files/2021-07/ACTIV_SARS-CoV-2_Small_Animal_Models_Field_Guide_11.30.20_vF.pdf

<1999 DTRA
DHS:- BioWatch
-Project Biosheild Act-2004
-9/11 Act 2007
Nunn-Lugar Expansion Act 2012
-P3, P2, CWMD
Operation Warp Speed
HHS:PHEMCE, PAHPA, PAHPRIA, PREP ACT



ACCELERATING COVID19 THERAPEUTIC INTERVENTIONS AND VACCINES [ACTIV]

CDA FREQUENTLY ASKED QUESTIONS (FAQ)

https://fnih.org/sites/default/file/pdf/ACTIV_Clinical_and_Preclinical_Candidate_Compound_Portal_Submissions_%20FAQs.pdf

ACTIV Overview

LAUNCH

On April 17, NIH announced the launch of a public-private partnership, **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

MISSION

Develop a coordinated research response to **speed COVID-19 treatment and vaccine options**

https://fnih.org/what-we-do/programs/activ-partnership
https://www.nih.gov/research-training/medical-research-initiatives/activ

FNIH

FAQs (1/5)

CDA?

What is ACTIV?

- **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)** is public-private partnership that develops coordinated research strategies for prioritizing and speeding development of the most promising treatments and vaccines for COVID-19.

Why am I being contacted by ACTIV and asked to sign a CDA?

- You submitted a compound via the ACTIV COVID-19 Clinical & Preclinical Candidate Compound Portal and either (1) your survey submission indicated that data essential to evaluate your candidate compound requires a CDA, or (2) your candidate compound was already reviewed, and the panel is asking for additional data for consideration.

Can I make modifications to the CDA?

- The ACTIV CDA is a standard template used for all submissions that require confidentiality agreements. The legal team at FNIH will review any proposed modifications to the CDA, however, this will delay the review process of your candidate compound.

Does the ACTIV prioritization process and CDA guarantee reviewer confidentiality?

- Our reviewers have a confidentiality agreement that binds them to the confidentiality within the CDA.

https://fnih.org/sites/default/files/pdf/ACTIV_Clinical_and_Preclinical_Candidate_Compound_Portal_Submissions_%20FAQs.pdf

What is a CDA?

CDA is essentially another word for "NDA", or Nondisclosure Agreement. CDA stands for Confidentiality Disclosure Agreement.

What does "CDA" mean in terms of covid-19 vaccines made through the ACTIV program

purposes, but do not want to be disclosed to third parties [1]. In the case of the ACTIV program, a CDA is required for entities that submit compounds for consideration as potential COVID-19 treatments or vaccines [1] [2]. The CDA ensures that the submitted compounds and related information are kept confidential and not disclosed to third parties without the consent of the submitting entity [1] [2].

1 fnih 2 policycommons

ACTIV Stakeholders

ACTIV is being coordinated by the Foundation for the National Institutes of Health (FNIH), and has brought together multiple partners from government, industry and non-profits.

8
Government Partners

20
Industry Partners

3
Non-Profits



BARDA
CDC
EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH
FDA U.S. FOOD & DRUG ADMINISTRATION
NIH
FNIH

abbvie
AMGEN
AstraZeneca
Bristol-Myers Squibb
Eisai
Lilly
evotec
gsk
Johnson & Johnson
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Former Chief Medical Officer and EVP, Pfizer Inc.

Pfizer



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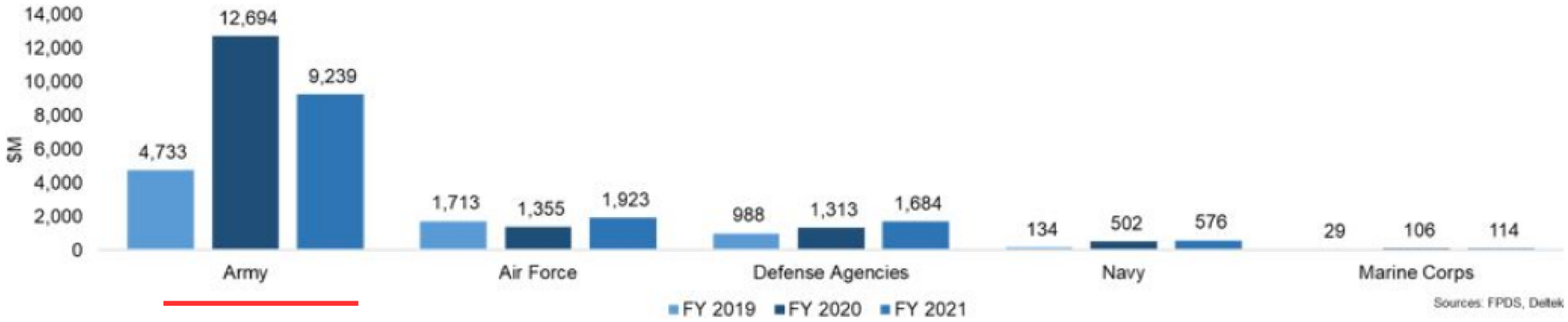
Exhibit 1: FDA's active COVID-19 partnerships with other U.S. government agencies[39]

Program name	Partners (all include FDA)	Program objectives
RADx	NIH National Institutes of Health	To **speed innovation** in the development, commercialization, and implementation of technologies for **COVID-19 testing**
ACTIV	NIH National Institutes of Health	To develop a coordinated research strategy for **prioritizing and speeding development of the most promising treatments and vaccines** through public-private partnerships
Operation Quack Hack		To **protect consumers from fraudulent medical products** by leveraging Agency expertise and advanced analytics
MOU on food supply	USDA	To establish a process by which determinations will be made about circumstances **in which USDA could exercise its authority under the DPA** over certain FDA-regulated entities to help prevent interruptions at food facilities
Collaboration on antibody tests	NIH NIAID; NIH National Cancer Institute; CDC	To establish a capability at NIH to **evaluate serological tests** for developers (including tests already available for use, as well as tests not yet on the market where additional validation data is needed to support an EUA)
Serology studies workshop	NIH NIAID; NIH National Cancer Institute; CDC; NIH National Heart, Lung, and Blood Institute; BARDA	To explore strategies to **address key scientific opportunities for serology testing** to address COVID-19
MOU on advanced manufacturing	NIH National Institutes of Health	To **facilitate information-sharing regarding the use of 3D printing and other advanced manufacturing technologies** in the context of personal protective equipment (PPE) and other medical device parts.
Vaccine safety monitoring	CDC	To **expand safety systems** including CDC's V-safe and National Healthcare Safety Network (NHSN)

Total DOD OTA Spending by Organization

When it comes to OTA-related spending, the Army stands head and shoulders above the rest of the DOD. This is true regardless if the good or service being purchased is IT-related or not.

Recommends companies use the Army for OTA's to "maximize its earning potential"



The Army outspends all of the rest of DOD on OTAs by a lot every year. The discrepancy reached a high point in FY 2020 when the Army spent nearly four-times as much on its OTA projects than all of the other DOD organizations combined. This ratio of Army to DOD OTA spending decreased to just over two-times in FY 2021 as the Army reduced its spending while other parts of the DOD slightly increased theirs.

The bottom line is that if a company wants to maximize its earning potential doing OTA-related work it really needs to be laser-focused on working with the Army, and then the Air Force, before any other part of the department.

NIH has announced two major research initiatives related to COVID-19. Announced on April 17, 2020, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) is a public-private partnership with several companies and federal agencies that aims to accelerate research and development on new vaccines and therapeutics by prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes, and leveraging the assets of partners for new products.[31] The Rapid Acceleration of Diagnostics (RADx) initiative announced on April 29 is a prize competition that aims to incentivize the development of new diagnostics for COVID-19.[32]



About MPP

The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a long-acting technology and two experimental oral antiviral treatments for COVID-19. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government and SDC. More information at https://medicinespatentpool.org/ and follow us on Twitter, LinkedIn and YouTube.

"The Medicines Patent Pool was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in low- and middle-income countries through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."

Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization

https://medicinespatentpool.org/



INVESTMENT FIRM

Medical CBRN Defense Consort.

Summary | Investments | People | Techno

About

Medical CBRN Defense Consortium was forme in response to the Government's expressed interest for an Other Transaction Agreement (OTA).

Summerville, South Carolina, United States

11-50

Government Office

www.medcbrn.org

98,793

Highlights

Investments
1

Patent pool

In patent law, a patent pool is a consortium of at least two companies agreeing to cross-license patents relating to a particular technology. The creation of a patent pool can save patentees and licensees time and money, and, in case of blocking patents, it may also be the only reasonable method for making the invention available to the public. Competition law issues are usually important when a large consortium is formed.

W More at Wikipedia

Repurposing a Defense Department consortium

Advance Technology International manages contracts and facilitates dealings with the government for several consortia of academics, companies and more, using OTAs.

In March and early April, the Department of Defense talked with ATI about a consortium of academics and companies that it manages called the Medical CBRN Defense Consortium, which is tasked with developing medical countermeasures to threats against the military. The Department of Defense, a partner in Operation Warp Speed, already had an overarching OTA with ATI concerning this group. To expand it for the COVID-19 response was a matter of adding more money and issuing a request for proposals concerning coronavirus vaccines and other COVID-19 items.

Many were OTAs that weakened or excluded Bayh-Dole clauses, which, among other things, allow the government to "march in" and take control of a drug or vaccine if a manufacturer that received federal funding engages in price gouging, for example.

"When asked about whether these contracts could be disclosed to the public under public records requests, he said *it was up to the government.*"

Tuohy says the consortium was established with a flexible mission, adding that OTAs often get a bad rap, but they don't deserve it. Even if the contracts don't include things like the Bayh-Dole protections, he says they often have similar replacement language. When asked about whether these contracts could be disclosed to the public under public records requests, he said it was up to the government. ATI couldn't point to an example of one of its contracts to consortium members being disclosed this way, but this may have happened without it being made aware.

OTA
for Prototype
Agreement

Merck Sharp &
Dohme Corp

NATICK: (ACC-Army,
Aberdeen Proving
Grounds MA

December 2020
W911QY-21-0-0001
$355,562,292.00

OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT

BETWEEN

Merck Sharp & Dohme Corp (Awardee)
2000 Galloping Hill Rd.
Kenilworth, NJ 07033-1310
DUNS Number: 001317601
CAGE Code: 6B2S4

And

NATICK CONTRACTING DIVISION (Government)
15 General Greene Ave.
Natick, MA 01760

Effective Date:	**2 December 2020**
Agreement Number:	**W911QY-21-9-0001**
Total Amount of the Agreement:	**$355,562,292.00**

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

21 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" (Pfizer, Inc.)

REF: Prizer Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 20 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Pfizer, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Pfizer, Inc. to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Pfizer, Inc.'s proposal for "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.'s proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed $1,950,097,500.00. The break-out of the costs is as follows: $1,950,000,000.00 to perform project efforts included in the SOW

July 2020

Army Contracting Command

Pfizer Vaccine

ATI (Advanced Technology International) Contract Manager

Are there any other companies that have used OTA technology for their COVID-19 vaccines

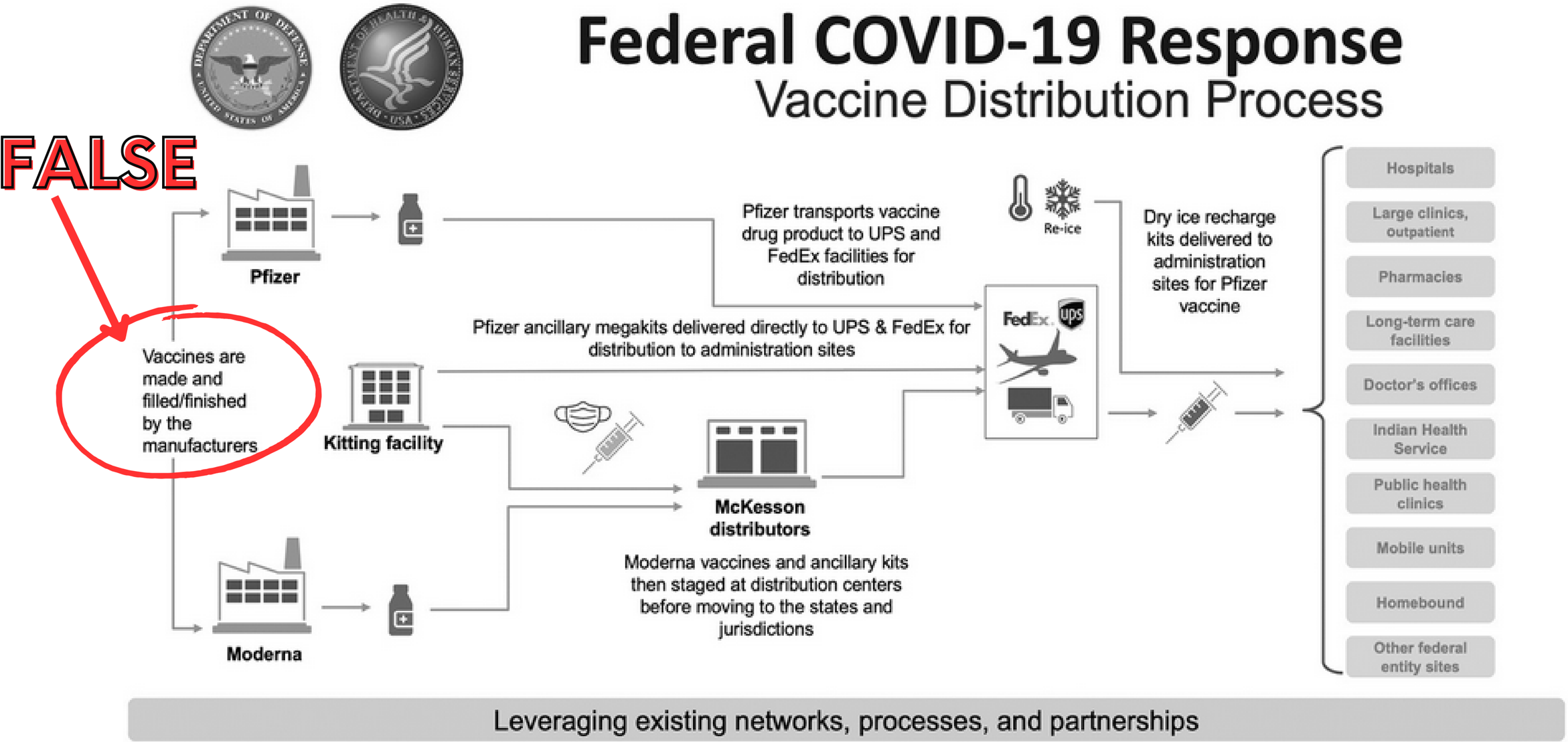
↘ PERPLEXITY

Yes, there are other companies that have used OTA technology for their COVID-19 vaccines. The U.S. government has used Other Transaction Authority (OTA) agreements to work with private companies to develop new technologies or products, including COVID-19 vaccines. Here are some examples:

- Johnson & Johnson: The U.S. government awarded Johnson & Johnson a $1 billion OTA agreement to develop and manufacture a COVID-19 vaccine [1]. The agreement provided for the delivery of 100 million doses of the vaccine, with an option for the government to purchase an additional 200 million doses [1].
- AstraZeneca: The U.S. government awarded AstraZeneca a $1.2 billion OTA agreement to develop and manufacture a COVID-19 vaccine [2]. The agreement provided for the delivery of 300 million doses of the vaccine [2].
- Sanofi and GlaxoSmithKline: The U.S. government awarded Sanofi and GlaxoSmithKline a $2.1 billion OTA agreement to develop and manufacture a COVID-19 vaccine [3]. The agreement provided for the delivery of 100 million doses of the vaccine, with an option for the government to purchase an additional 500 million doses [3].

Overall, OTA agreements have been used by the U.S. government to work with private companies to develop COVID-19 vaccines and other technologies. These agreements provide the government with access to cutting-edge technologies and products that might not be available through traditional procurement methods [4].

Figure 2. COVID-19 response and vaccine distribution process



https://www.usmcu.edu/Outreach/Marine-Corps-University-Press/MCU-Journal/JAMS-vol-13-no-1/Operation-Warp-Speed/

FOR IMMEDIATE RELEASE
October 18, 2022

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Announces Actions to Counter Biological Threats, Enhance Pandemic Preparedness, and Achieve Health Security

The U.S. Department of Health and Human Services (HHS) today announced actions the department will take following National Security Memorandum 15, signed by President Biden, directing implementation of the 2022 *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* - PDF.

https://www.hhs.gov/about/news/2022/10/18/hhs-announces-actions-to-counter-biological-threats-enhance-pandemic-preparedness-and-achieve-health-security.html

Strengthening early warning and awareness of pandemics and biological threats

HHS will lead efforts to improve early warning of biological threats and data availability to support real-time, evidence-based decision-making, including:

- **Improving disease detection and reporting:** Develop domestic capability to improve detection and reporting of disease outbreaks, conduct rapid genomic sequencing and analysis, and support the development of global systems to share information, data, and samples internationally and across industry sectors. Such improvements are essential to prevent or limit the impact of significant biological incidents, both domestically and internationally.
- **Accelerating advanced detection technologies:** Accelerate research and innovation for advanced biodetection capabilities for clinical and environmental settings, to enable large-scale, affordable, and routine surveillance for novel pathogens.
- **Enhancing hospital data collection:** Maintain and enhance an enduring domestic all-hazards hospital data collection capability to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations at the federal, state, local, tribal, and territorial levels.
- **Improving data analysis to enhance early warning:** Enhance capacity for rapid analysis, modeling, baselining, forecasting, and reporting to monitor and evaluate the health threat landscape, using a One Health approach, and improve early warning capabilities.

"ONE HEALTH"

https://www.hhs.gov/about/news/2022/10/18/hhs-announces-actions-to-counter-biological-threats-enhance-pandemic-preparedness-and-achieve-health-security.html

What is Operation Warp Speed and how does it differ from typical R&D?

Operation Warp Speed is a new national program to "accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics."[27] The program is intended to coordinate MCM efforts "between components of HHS, including CDC, FDA, NIH, and BARDA; the Department of Defense; private firms; and other federal agencies." Its stated goal is to accelerate selected MCM testing while developing manufacturing infrastructure to allow mass distribution faster than would be possible otherwise (see **Figure 1**). Not all government-supported countermeasures will participate in Operation Warp Speed.

The **Department of Defense (DOD)** operates several medical research and MCM development efforts, including through the Congressionally Directed Medical Research Program (CDMRP), the U.S. Army Medical Research and Development Command (USAMRDC), and the Defense Advanced Research Projects Agency (DARPA). For example, DARPA's Pandemic Prevention Platform program is focused on developing a platform that would aid in the rapid development of new MCMs in response to the identification of any known or unknown infectious threat.[15]

CDC, NIH, and FDA participate in the **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)**, along with DOD, the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). The PHEMCE, under the leadership of ASPR, facilitates interagency coordination and strategy for the development, regulation, and availability of medical countermeasures in preparation for public health emergencies such as infectious disease outbreaks. As required by Public Health Service Act (PHSA) Section 2811,[16] the PHEMCE assesses and updates a strategy plan annually for MCM preparedness.[17]

https://www.usmcu.edu/Outreach/Marine-Corps-University-Press/MCU-Journal/JAMS-vol-13-no-1/Operation-Warp-Speed/

February 2023

GAO Highlights

Highlights of GAO-23-105713, a report to congressional committees

PUBLIC HEALTH PREPAREDNESS

HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks

Why GAO Did This Study

The COVID-19 pandemic and other recent public health emergencies highlight the threat of widespread illness and death posed by new and emerging infectious diseases. GAO has designated HHS's leadership and coordination of public health emergencies as a high-risk area due to the need to be prepared for, and effectively respond to, future public health threats.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report examines (1) how HHS used CIADM program funds prior to and during the COVID-19 pandemic, (2) what challenges affected the CIADM program's effectiveness in developing and manufacturing countermeasures, and (3) how HHS plans to use its new program model to address the challenges of the CIADM program.

To address these objectives, GAO

What GAO Found

In 2012, the Department of Health and Human Services (HHS) established a program to improve domestic infrastructure and expertise to produce medical countermeasures—such as drugs and vaccines—in response to public health emergencies. This program, known as the Centers for Innovation in Advanced Development and Manufacturing (CIADM), was originally composed of three sites responsible for, among other things, rapidly producing countermeasures for a pandemic. During the period prior to the COVID-19 pandemic, HHS funded the sites to produce small batches of drug substances for other manufacturers. During the COVID-19 pandemic, HHS provided increased funding to reserve capacity to produce products at a larger scale to aid the pandemic response. However, HHS said that the sites faced challenges reliably producing products at a larger scale, such as poor quality control, that led to the eventual shutdown of one site due to cross-contamination.

An internal HHS review found that a lack of regular manufacturing work from either HHS or other manufacturers prevented the sites from developing the capability to rapidly produce countermeasures at a large scale as the program intended. HHS and site officials identified several reasons for this underuse, including a lack of dedicated funding from HHS and challenges attracting external manufacturers to use the sites for countermeasure production.

HHS is ending the CIADM program and plans to transition to a new program model—the National Biopharmaceutical Manufacturing Partnership (BioMaP). BioMaP is early in its development, and it is unclear how BioMaP will address some of the challenges faced by the CIADM program, as in the following examples.

GAO 1

examined HHS documents and leading practices for managing program risks and interviewed and reviewed written correspondence with representatives from HHS and the three CIADM sites.

What GAO Recommends

GAO is recommending that HHS incorporate into the development of its new program model an approach to systematically assess, and respond to, known challenges and risks associated with advanced development and manufacturing of medical countermeasures. We provided a draft of this report to HHS for review and comment. HHS concurred with our recommendation.

View GAO-23-105713. For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

- BioMaP is expected to use a different contracting structure intended to provide more incentives for industry partners to participate. However, this different structure requires additional expertise to manage effectively. Moreover, HHS told GAO that its contracting staff had previously faced resource challenges using this different contracting structure for other programs during the COVID-19 pandemic. HHS officials said in April 2022 that the agency has half the contracting staff needed to manage its contracting portfolio. This creates the risk that the agency may not have enough resources and expertise to manage this different structure effectively.
- HHS does not have a sustainable source of funding for the new program model, and it has not yet developed detailed plans or budgets. HHS officials said that, without sustained funding for BioMaP or a similar program, the agency would be unprepared to respond to the next pandemic.

As HHS is developing its plans for a new program model for countermeasure production, incorporating an approach to address these challenges and risks would provide HHS with greater assurance that it can avoid repeating the challenges of the CIADM program.

GAO 2

https://www.gao.gov/assets/gao-23-105713.pdf

[32]For example, as part of the COVID-19 response, the government supported multiple manufacturing technologies during vaccine development in order to mitigate the risk that any one platform or specific vaccine candidate could fail because of problems with safety, efficacy, industrial manufacturability, or scheduling factors. This strategy included two vaccine platforms that had not previously been used in a licensed vaccine, but could theoretically be quickly adapted to COVID-19 and scaled up rapidly (i.e., the mRNA platform and replication-defective live-vector platform), and one platform that had been proven (i.e., the recombinant-subunit-adjuvanted protein platform). For more information, see GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO-21-319 (Washington, D.C.: Feb. 11, 2021).

https://www.gao.gov/assets/gao-23-105713.pdf

FDA Inspections and Current Good Manufacturing Practices for Vaccines

The Food and Drug Administration (FDA) ensures the quality of vaccines marketed in the U.S. by monitoring manufacturing facilities' compliance with current good manufacturing practices. Current good manufacturing practices are FDA regulations that contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a product. See 21 C.F.R. Parts 210 and 211 (2021). FDA considers compliance with current good manufacturing practices as part of its review of new product applications, as well as during post-marketing inspections.

Other Transaction Agreements (OTA) Use During COVID-19

Most of the COVID-19 OTA dollars were obligated in July 2020 and driven by vaccine awards. Of the $12.5 billion the Departments of Defense, Health and Human Services (HHS), and Homeland Security obligated for COVID-19 OTAs, $8.9 billion or 71 percent was for vaccine development—including clinical trials—and manufacturing efforts. The remaining $3.6 billion was for medical research and development and other nonvaccine products and services. HHS obligated at least $1.6 billion on COVID-19-related OTAs from March 2020 through March 2021—primarily to help accelerate vaccine development and manufacturing. However, this is an underreported figure because HHS misreported its OTAs as procurement contracts. From November 2020 through March 2021, OTA obligations were comparatively not as significant as earlier in the pandemic. This was, in part, because additional vaccine doses were acquired using procurement contracts instead of OTAs.

Source: GAO-21-501. | GAO-23-105713

UNC's 2021 Symposium for Research Administrators

Agencies authorized to fund OTAs

- Dept of Defense (DoD) – all branches (DARPA, AFRL)
- U.S. Dept of Transportation (DOT)
  - Federal Aviation Administration (FAA)
- U.S. Dept of Homeland Security (DHS)
  - Transportation Security Administration (TSA)
  - DHS Domestic Nuclear Detection Office (DNDO)
- U.S. Dept of Health and Human Services (DHHS)
  - National Institutes of Health (NIH)
- U.S. Dept of Energy
  - DOE Advanced Research Projects Agency-Energy (ARPA-E)
- National Aeronautics and Space Administration (NASA)

What are the 3 types of OTAs?

R&D (Research and Development)

- Medical research
- Pharmaceuticals
- Community engagement

Prototype activities

- Military technology improvements
- Energy development and security research
- Oil and pipeline safety

Production activities

- May follow on after prototype activity is completed



R&D (Research and Development) OTAs

- Used for basic, applied, and advanced research
- Should allow for greater speed, flexibility, and accessibility for research activities
- Reduces the burden of Government regulatory overhead allowing for a more competitive environment within the **commercial** (non-defense) sector
- Can address IP concerns and cost accounting standards by providing terms that may be more desirable to commercial partnerships

Prototype and Production OTAs

- Prototype OTAs allow for projects that are directly relevant to weapons or weapons systems proposed to be acquired or developed by the Department of Defense.

- Production OTAs allow for a non-competitive, follow-on OTA to the prototype agreement that has been successfully completed. Government must give advanced consideration, and notice is to be made of the potential follow-on OTA. Therefore, all solicitations will include a notice that there is the future possibility of a follow-on OTA.

https://acqnotes.com/acqnote/careerfields/other-transaction-authority-ota

OTA Structures

- OTAs' structure allows the government flexibility to include, amend, or exclude traditional procurement clauses.

- Different OTA structures:
  - Direct relationship between single government agency and provider
  - Joint ventures
  - Partnerships
  - Multiple agencies collaborating to fund an agreement across multiple providers
  - Consortium Pass-through

Other positive considerations for the federal use of an OTA

OTA's do not include onerous contracting obligations found in a federal procurement contract such as:

- Bayh-Dohl Act;
- Buy American Act;
- Contract Disputes Act;
- Truthful Cost or Pricing Act;
- Cost Accounting Standards

National Institutes of Health (NIH) OTA Structure

National Institutes of Health (NIH)

- Direct flow of funds to UNC
- Pass-thru funding to RTI (Contract Research Organization aka CRO)

Department of Defense (DOD) OTA Structure

- Department of Defense typically funds via a Consortium Agreement which is defined as an organized group focusing on a specific technology area (non-profits, academia, or contractors)

- Pass-through consortiums/CRO from which UNC has received funding:
    - Medical Technology Enterprise Consortium (MTEC)
    - Medical CBRN Defense Consortium (MCDC)
    - Nano-Bio Materials Consortium (NBMC)

explain OTAs in the context of medical counter measures

↘ PERPLEXITY

In the context of medical countermeasures, Other Transaction Authorities (OTAs) are a type of procurement contract that can be used to support the development and manufacturing of medical countermeasures [1] [2]. Here are some key points to understand about OTAs and medical countermeasures:

- Medical countermeasures (MCMs) are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease [3].
- The FDA works with partners at all levels of government to support MCM-related public health preparedness and response efforts [3].
- OTAs are not required to include terms and conditions that are typically required when using traditional procurement contracts subject to the Federal Acquisition Regulation (FAR) [1].
- OTAs can be used to support the development and manufacturing of medical countermeasures [1] [2].
- The ultimate purpose of an OTA for medical countermeasures is to develop a countermeasure against a specific disease or condition by rapidly obtaining research and development services [2].
- Uncertainty is a common cognitive strategy when dealing with medical countermeasures, and information seeking is an important part of public understanding of medical countermeasures [4].

Overall, OTAs are one way that the government can support the development and manufacturing of medical countermeasures in the event of a public health emergency.

1 gao 2 hhs 3 fda 4 nih

OTA's:

Other Transactional Authority

NOT- required to include terms and conditions that are traditionally required for Federal Acquisition Regulations.

what role did the DoD have in the covid-19 vaccines?

The Department of Defense (DoD) played a significant role in the development, manufacturing, and distribution of COVID-19 vaccines in the United States. Here are some key points to understand about the DoD's role in COVID-19 vaccines:

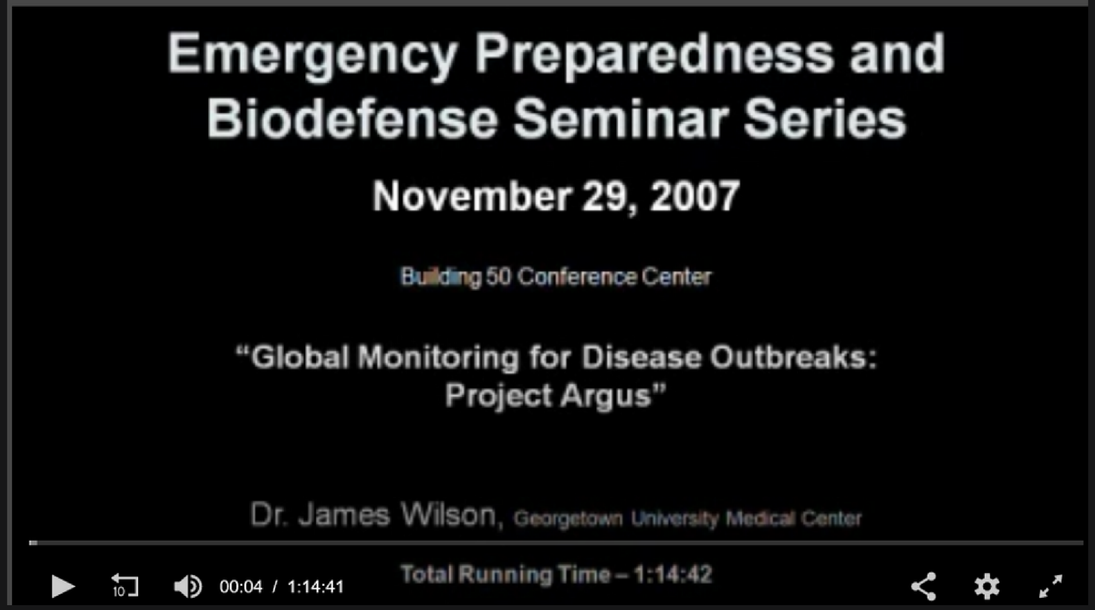
- Since May 2020, federal efforts to speed up the development, manufacturing, and distribution of COVID-19 vaccines have been led by the Departments of Health and Human Services (HHS) and Defense (DoD) through a partnership called Operation Warp Speed [1] [2].
- The DoD COVID-19 Vaccination Plan served as the DoD's integrated global response plan to distribute and administer the COVID-19 vaccine [3].
- The DoD worked with vaccine companies to develop COVID-19 vaccines and made available a sufficient supply for all eligible people in the nation [1].
- The DoD was involved in the transfer of remaining COVID-19 vaccine manufacturing assets from the DoD to HHS in 2022 [1].
- In January 2023, Defense Secretary Lloyd J. Austin III rescinded the Pentagon COVID-19 vaccine mandate, affecting thousands of Airmen and Guardians [4].

- The DoD was involved in the manufacturing of COVID-19 vaccines through the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG), which worked with vaccine companies to develop COVID-19 vaccines and made available a sufficient supply for all eligible people in the nation [1].
- The CAG dissolved and transitioned its responsibilities, including DOD-led vaccine activities, to HHS by December 31, 2021, as required by an April 2021 memorandum of understanding between the two departments [1].
- DARPA, a research and development agency of the DoD, contributed to preventing future COVID-19 infections through novel vaccine technology [2].

What was the organizational structure of Operation Warp Speed

- Operation Warp Speed was a public-private partnership that aimed to coordinate existing efforts with new ones [1].
- The program was initially funded with about $10 billion from the CARES Act (Coronavirus Aid, Relief, and Economic Security) passed by the United States Congress on March 27, 2020 [1].
- The program was led by Dr. Moncef Slaoui, the chief adviser, and General Gustave Perna, the chief operating officer [2].
- The organizational chart of Operation Warp Speed revealed a highly structured organization in which military personnel vastly outnumbered civilian scientists [2].
- The program had three focus areas: developing and manufacturing vaccines, delivering vaccines, and ensuring safe and effective vaccine administration [3].

Global Monitoring for Disease Outbreaks: Project Argus



Link: https://videocast.nih.gov/watch=6337

Air date: Thursday, November 29, 2007, 3:30:00 PM
Time displayed is Eastern Time, Washington DC Local

Views: Total views: 361 * This only includes stats from October 2011 and forward.

Category: Special

Runtime: 01:14:42

Description: Dr. Wilson is a faculty member in the departments of pediatrics, radiology, microbiology and immunology at Georgetown University Medical Center, where he directs Project Argus, a global detection and tracking system for the early detection of biological events. His presentation will focus on how non-traditional data can be used to detect outbreaks of human, animal and plant diseases. More information is available at http://biodefense.georgetown.edu/projects/argus.aspx

What were the incentives offered to private companies to participate in Operation Warp Speed

The incentives offered to private companies to participate in Operation Warp Speed were designed to encourage faster vaccine development and manufacturing. Here are some key points to understand about the incentives offered to private companies:

- The funding mechanism utilized by Operation Warp Speed was based on incentive rather than government control [1].
- Private companies were provided with funding and support to develop and manufacture COVID-19 vaccines [2].
- The program provided logistical support to ensure the efficient distribution and administration of COVID-19 vaccines [3].
- Private companies were also provided with incentives to encourage faster vaccine development and manufacturing [2].
- The benefits for companies who landed an Operation Warp Speed contract went beyond just money, according to one of the companies with a contract [2].
- SiO2 Materials Science, an Auburn, Ala.-based company that is making vials for the effort, used its status as an Operation Warp Speed grantee to force a vendor to cut production time from 75 days to just seven. It also leveraged its contract with Warp Speed to get its power turned on in the midst of a massive outage in just minutes [2].
- Governments can offer incentives to install extra capacity and stockpile inputs to encourage faster vaccine manufacturing [4].

Are there any politicians that have stocks in Moderna?

↘ PERPLEXITY

There have been reports of politicians buying and selling stocks in Moderna, a biotechnology company that has developed a COVID-19 vaccine. Here are some examples:

- A senior aide to Sen. Mitch McConnell made a mid-January purchase of Moderna, Inc., a biotechnology company that had four days earlier announced it would begin developing a coronavirus vaccine [1].
- Rep. Josh Gottheimer, a Democrat of New Jersey, held Moderna stock. In May 2020, he sold up to $15,000 worth of his shares [2].
- The chancellor, Rishi Sunak, co-founded a hedge fund that has a $500m investment in Moderna, which accounts for around 20% of all the money it manages, about $2.5bn [3].
- According to OpenSecrets, Rep. Jim Sensenbrenner (R-Wis.) reported holding between $1 million and $5 million in Pfizer stock, which is another company that has developed a COVID-19 vaccine [4].
- Consumer Watchdog reported that 38 senators had up to $13.4 million in pharmaceutical stock, but it is unclear if any of these stocks were specifically in Moderna [5].

It is worth noting that not all of these transactions necessarily constitute insider trading or other illegal activities. However, there have been concerns about the potential for conflicts of interest when politicians hold stocks in companies that are involved in developing COVID-19 vaccines or treatments.

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which lawmakers have bought or sold Moderna stocks

↘ PERPLEXITY

According to an analysis by Business Insider, at least 75 federal lawmakers held shares of Moderna, Johnson & Johnson, or Pfizer in 2020 [1]. Rep. Josh Gottheimer, a Democrat of New Jersey, was the only other lawmaker who held Moderna stock. In May 2020, he sold up to $15,000 worth of his shares [1]. Additionally, a senior aide to Sen. Mitch McConnell made a mid-January purchase of Moderna, Inc., a biotechnology company that had four days earlier announced it would begin developing a coronavirus vaccine [2]. However, it is worth noting that not all of these transactions necessarily constitute insider trading or other illegal activities. It is illegal for lawmakers and aides to trade stocks based on private information, but they are allowed to buy and sell shares based on public information they absorb on Capitol Hill so long as they disclose those trades within 30 days [2]. The potential for conflicts in stock trading by members of Congress has long drawn criticism, especially when particularly blatant cases emerge [3].

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was bill and melinda gates involved in Operation WArp Speed?

↘ PERPLEXITY

There is no evidence that Bill and Melinda Gates were directly involved in Operation Warp Speed (OWS), which was a U.S. public-private partnership to accelerate the development, manufacture, and distribution of COVID-19 vaccines, therapeutics, and diagnostics announced by President Trump on May 15, 2020 [1]. However, the Bill & Melinda Gates Foundation has been involved in several initiatives related to COVID-19 vaccine development and distribution, including providing more than $2 billion to support the global response to COVID-19, investing in deep technical expertise and novel platforms in vaccine development and manufacturing to accelerate innovation for better, faster, and cheaper vaccines, and supporting the Gavi COVAX Advance Market Commitment to help ensure that COVID-19 vaccines are accessible and affordable in low- and middle-income countries [2] [3].

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- Sentinel
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Project Argus

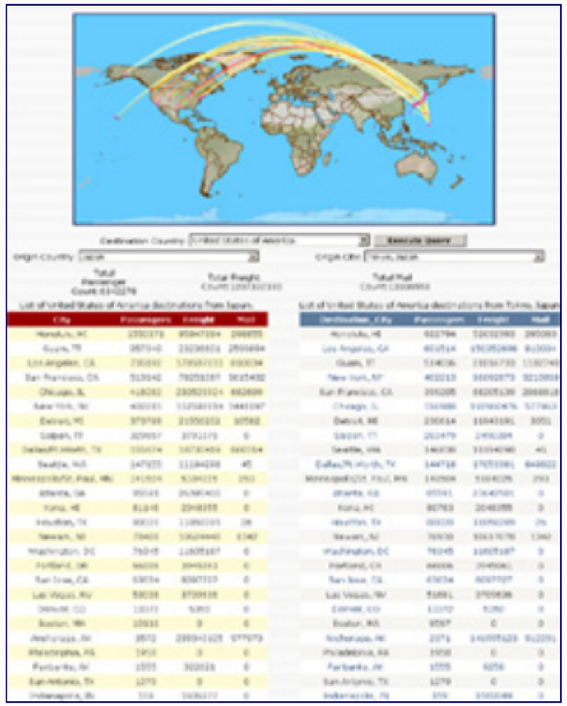
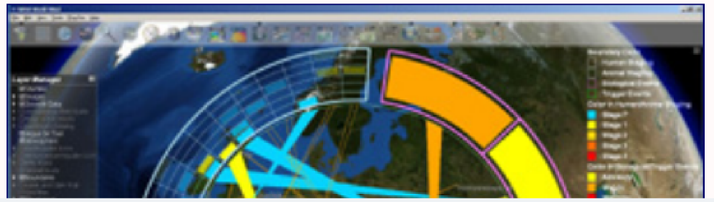


Fig. 1: Air-Transportation Query Page

The frequency of biological events with a potential impact on homeland security is increasing, and current disease surveillance systems in the United States (U.S.) have been inefficient in their capacity to detect these events in a timely fashion. The clear and present danger to the United States spans infectious diseases of humans, animals, and plants.

Indications and Warnings (I&Ws) alert U.S. responders of an imminent bioevent weeks to months in advance. I&Ws are markers occurring globally, outside of U.S. borders, before an outbreak can affect U.S. interests, forces, citizens, or territory, thus allowing the U.S. time to respond. In effect, I&Ws can prime the national response infrastructure by alerting agencies of an evolving threat that could ultimately be catastrophic. Retrospective analyses of major bioevents have demonstrated the presence of multiple I&Ws were present in multiple data sources weeks to months in advance, which were not recognized and utilized properly by the national response community.



For the U.S. to meet present and future biothreats that span agricultural, animal, and human considerations, an integrative strategy for information discovery,

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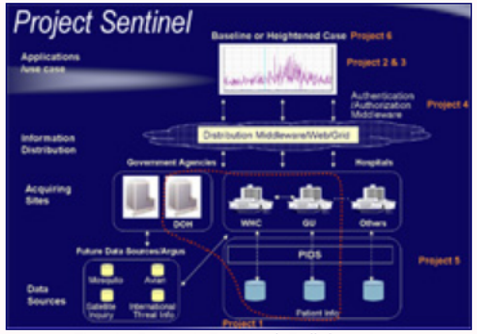


Fig. 1: Project Sentinel Collaboratory

The Project Sentinel Collaboratory, funded by the National Library of Medicine, Georgetown University and the Emergency Departments of MedStar Washington Hospital Center, and MedStar Georgetown University Hospital, will build and deploy a data-centric collaboratory to collect and an alyze data from hospitals, clinics, weather services, satellites, mosquito collections, veterinary clinics and other sources in order to develop indications and warnings (I&Ws) of emerging threats to human health. Detection of appropriate I&Ws will allow more time for various authorities to prepare corresponding responses to potential threats.

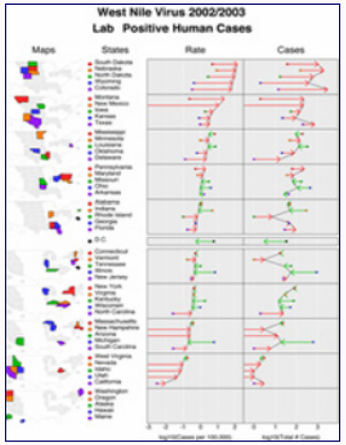


Fig. 2: West Nile Virus Lab Data

The Project Sentinel Collaboratory will exploit emerging new concepts in information technology, such as middleware, network weather services, electronic authorization and authentication approaches, and grid services to manage novel disparate data streams and evaluate network-dependent applications. Appropriate use of these tools will enhance interoperability, improve protection of data security, and increase the speed at which essential and useful information can be communicated among authorized users. Initial users of the system will include public health authorities at the DC Department of Public Health, researchers, and physicians from participating hospitals, emergency departments and community clinics. This project is a key part of a prototype integrated biodefense system currently under development by the Division of Integrated Biodefense.

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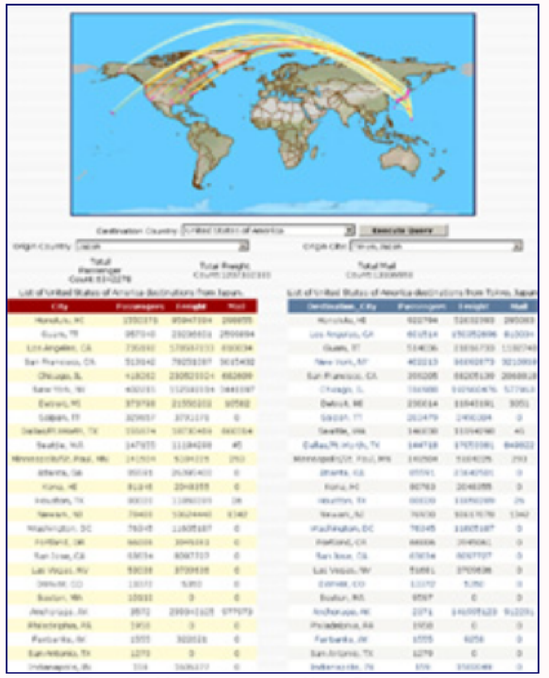


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For the U.S. to meet present and future biothreats that span agricultural, animal, and human considerations, an integrative strategy for information discovery, exploitation, and effective proactive use by the response community is critical. I&Ws provide a key component for integration within the U.S. biosurveillance portfolio, enabling earlier warning potential. Project Argus is the first attempt to integrate I&Ws in effort to detect catastrophic bioevents on an international scale. The Argus system serves as a primer for U.S. countermeasure response plans in the context of a potentially catastrophic bioevent. Project ARGUS is jointly funded by the US Army Medical Research and Materiel Command Telemedicine and Advanced Technology Research Center (USAMRMC-TATRC) and the Department of Homeland Security.

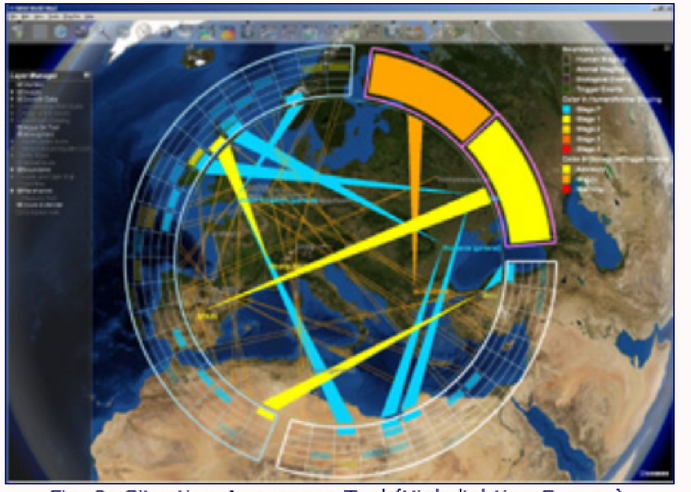


Fig. 2: Situation Awareness Tool (High-lighting Europe)

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What is the ISIS center at Georgetown University?

↘ PERPLEXITY

The ISIS Center at Georgetown University is not related to the terrorist organization ISIS. Instead, it stands for Imaging Science and Information Systems Center. It is a research center under the Department of Radiology at the Georgetown University Medical Center [1]. The center focuses on the development of advanced medical imaging technologies and information systems [2]. It was established in the 1980s and 1990s and was led by Seong K. Mun [3]. The center is not to be confused with the Center for Security Studies, which is another academic research center in the School of Foreign Service that offers a master's degree program [4].

1 idealist 2 georgetown 3 georgetown 4 georgetown

What is the outcome of the lawsuit between Georgetown College and the former employees over Project Argus patent rights

PERPLEXITY

Georgetown College sued two former employees who refused to give up their patent rights to inventions for "Project Argus," a federally funded global pandemic warning system [1]. The outcome of the lawsuit is unclear, as there are no recent reports on the case. However, the lawsuit suggests that Georgetown College claims ownership of the patent rights to Project Argus [1]. It is possible that the case was settled out of court or is still ongoing. There are no further details on the outcome of the lawsuit.

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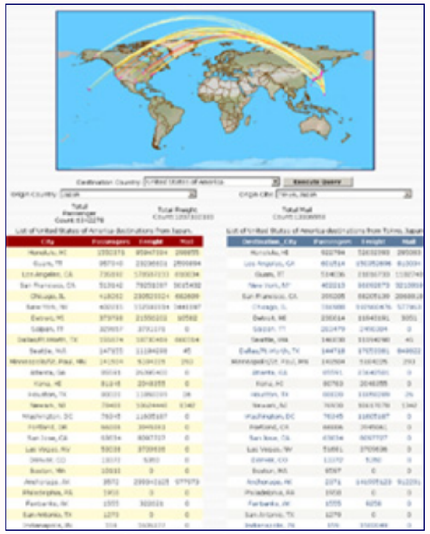


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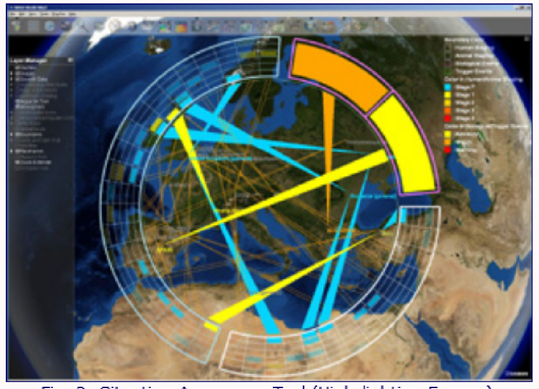


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